



Animal Welfare Institute

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Comments for Streamlining IACUC Review for Animal Activities

The Animal Welfare Institute (AWI) is not opposed to the overarching goal of reducing administrative burdens, but this cannot and should not come at the expense of animal welfare. Currently, OLAW and the USDA alone cannot realistically enforce compliance. There are currently two staff members in the OLAW Compliance Oversight Division¹ to cover 1,119 domestic institutions and 346 foreign institutions.² APHIS oversaw 13,376 licensees and registrants in 2022, including nearly 2,500 new registrants, (representing over 1.4 million AWA-covered animals)³ up from 11,785 licensees and registrants in 2021.⁴ Yet the number of animal welfare operations inspectors has declined during the same period from 122⁵ to 98,⁶ making the role of a robust IACUC all the more vital.

This low ratio of inspectors to the institutions and animals used for research makes proper enforcement impossible without reliable IACUC review. As such, “PHS Policy is based on a concept of enforced self-regulation.”⁷ “Veterinary inspectors from the U.S. Department of Agriculture cannot be present on a daily basis. However, their enforcement capability *can and should be enhanced by the Institutional Animal Committee.*”⁸ (Emphasis added) Therefore, IACUCs are the cornerstone of our system and bear the brunt of ensuring compliance. IACUCs are central to the proper functioning of our animal welfare framework and OLAW relies heavily on enforced self-regulation. Therefore, IACUCs should be strengthened, not weakened.

Any consideration in changes to administrative “burdens” needs to be contemplated through the lens of the animals’ interests, not just the interests of human society. Furthermore, an underlying foundation of the regulatory framework is that society has an inherent interest in proper animal welfare; one of the purposes of the IACUC is to “represent *society’s concerns regarding the welfare of animal subjects* used” in research.⁹ (Emphasis added) Indeed, this is an important function of the requirement for an unaffiliated IACUC member.¹⁰ These “burdens” exist for a reason and should only be “reduced” if they genuinely will not impact animal welfare. Reduction of administrative burdens cannot come at the expense of animal welfare; the goal of efficiency must always be secondary to animal protection. Specifically, this cannot result in the reduction of standards, or the creation of loopholes, for proper care and treatment of animals.

AWI is concerned that the proposed streamlining policies will lead to a reduction of standards and, consequently, diminished protections for research animals. Our specific concerns and suggestions are outlined below.

I. Proposed Guidance for Streamlining DMR

It is certainly true that designated member review (DMR) would reduce administrative burden and create a more efficient process given that it does not require an IACUC quorum. However, some of the proposed guidance for streamlining this process raise concerns about the safeguards to animal welfare in a more streamlined process. Our knowledge of potential alternatives to animal models in research and our understanding of animals' ability to feel pain and their cognitive abilities change very rapidly, making it unreasonable to expect that any one person will have all of that knowledge. For this reason, review by multiple members should be the preferred approach.

The proposed guidance says that IACUCs may "determine a reduced, but reasonable, time frame" for "concurrence by silent assent once the full time has elapsed" for a call for full committee review (FCR), such as "three instead of seven business days."¹¹ Silent "assent" may occur for a variety of reasons, including a situation where a member has not had time to review the proposal and determine whether to assent. Academics are busy; one 2017 study showed that "most faculty clock an average of 57 work hours per week."¹² Furthermore, research has shown that "individuals disproportionately stick with the status quo."¹³ Studies also indicate that "rates of consent are higher under presumed consent policies than under explicit consent policies"^{14 15} and that "small implementation decisions can substantially impact whether and how people interact with consent notices."^{16 17} This is only going to be exacerbated by an accelerated timeline, such as that suggested here, or the two-day window used by at least one university.¹⁸ **AWI suggests that, at minimum, IACUC members be required to acknowledge receipt of materials before being considered as having given "silent assent" to ensure that all members are at least aware of the materials and deadline to respond.**

Second, the proposed guidance suggests submissions may be "routed" to DMR to allow DMR to begin while the IACUC is provided time to call for FCR, although it cannot be finalized until the IACUC members have had a reasonable time to call for FCR or all IACUC members have responded.¹⁹ While this definitely would accelerate the process of approval, from an animal welfare perspective we are concerned that IACUC members may feel pressured to "assent" to a DMR that is already underway, especially if it is substantially completed and/or he or she is clearly in the minority in wanting FCR. **If this suggestion is adopted, we would request that the fact that the DMR is already in progress should not be disclosed to the other IACUC members in order to avoid this potential pressure.**

The guidance also suggests that the IACUC chairperson may "designate only one qualified member to conduct the review," which "may reduce the burden" because it eliminates requirements that "reviewers must be unanimous." However, we argue that the elimination of unanimous decisions is precisely why this suggestion raises concern – it vests final decision making in one reviewer. The potential for debate and dissension is specifically the benefit of having multiple reviewers of different backgrounds and expertise who can ensure that all potential problems are thoroughly considered. Indeed, the Animal Welfare Act "intends that facility personnel function as checks on each other and on the facility as a whole, and relies on the facility to monitor its own house."²⁰ This sort of internal "check" cannot be effectively accomplished by one person. Therefore, we strongly question whether such a change could ensure that animal welfare was not compromised. This is especially true if the proposed guidance that "designated member approval does not require subsequent reapproval by the IACUC at a convened meeting" is retained. At minimum, **we suggest the implementation of a mechanism of checks**

and balances to ensure that review by only one member is in some way reviewed by the other members, especially in the event of “silent assent” to DMR.

With regard to the suggestion that “the IACUC may determine the best means of documenting the DMR process from review to approval,” **AWI would encourage a suggested best-practices-based method of documentation to ensure rigorous standards and record keeping as well as a thorough review. In addition, we argue that such a standardized approach would in effect help reduce administrative burden by creating a routine set of standards that IACUC members could become familiar with and efficient at using.**

While the goal of reduced administrative burden is understandable, the combined proposals for streamlining DMR seem to create the opportunity for DMR to create a situation where review becomes *too* streamlined and proposals sail through review without adequate examination and safeguards. If all of the proposed mechanisms for streamlining are accepted, we can imagine a scenario where under a short time frame for a call for FCR leads several members of an IACUC to run out of time to thoroughly review the proposal, therefore silently “assenting” to DMR by default. The DMR would already be underway by then, reviewed by one qualified member, whose approval does not require subsequent reapproval by the IACUC. This process would allow an accelerated review that may be examined in depth by only one reviewer without a subsequent safeguard of further approval. We believe this is likely to encourage a rubber-stamping mentality, which would increase the likelihood of a negative impact on animal welfare to an unacceptable level, especially if the only benefit is a reduction in administrative time. Potential harm to animal welfare outweighs that benefit, and the IACUC framework is intended to be the bulwark against cutting corners.

II. Proposed Guidance for Streamlining DMR Subsequent to FCR

This proposal suggests that “neither a convened meeting nor a vote is necessary to propose a DMR subsequent to FCR policy” and that “members are not required to sign the policy.” **AWI believes that the minimal reduction in administrative burden by not requiring a vote on such a policy is significantly outweighed by the potential harm to animal welfare.** Similarly to our concerns about “silent assent” to DMR, the suggestion that giving each member an “opportunity to provide their input” prior to approval, thereby allowing a form of silent assent, rather than requiring an actual vote – a more affirmative assent – creates too much opportunity for policies to be approved without proper review and forethought. The marginal increase in administrative “burden” from holding a vote is not too onerous in light of the need for proper safeguards to animal welfare.

III. Proposed Guidance for Streamlining VVC

Similarly to the documentation requirements for DMR, **AWI would encourage a suggested best-practices method of documentation for VVC.** While the proposal that IACUCs have the “flexibility to determine the processing and documentation of VVC” would reduce administrative burden, as noted above, we believe that a best-practice-based documentation regime would encourage better record keeping and ensure proper review, especially in a situation where the veterinarian is not an employee of the institution. Furthermore, as noted above, a standard form for use in all reviews would help reduce administrative burden in that it would set standard expectations and practices that would allow for quick processing of the veterinarian’s review.

We also believe the IACUC should, at a minimum, receive notification of the VVC changes. Notification would give the IACUC members an opportunity to review the VVC, offering a safeguard against potential errors or misjudgments.

IV. Conflicts of Interest

The concerns outlined above are exacerbated by concerns about conflicts of interest.²¹ While OLAW policy states that “no member may participate in the IACUC review or approval of a research project in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum,”²² the situations considered to be conflict of interest usually cover instances where a “member’s personal biases may interfere with his or her impartial judgment, a member is involved in a competing research program, or access to funding or intellectual information may provide an unfair competitive advantage.”²³ This leaves a glaring hole for situations where the institution itself (to which all but one IACUC member belong) has a financial interest in the outcome and the pressures that may be associated with it.

With financial incentives, conflicts of interest are bound to arise. These conflicts become even more problematic when IACUC protocols are relaxed, particularly in a situation involving a single member doing a DMR. We believe that, given the critical role of IACUCs in protecting animal welfare and the potential pressures to “rubber stamp” a protocol, streamlining the IACUC process too far creates too much risk to animal welfare.

V. Conclusion

We believe the suggested flexibilities, particularly in combination with each other, are eroding IACUCs’ authority to the point where there is a risk that the spirit of the law is no longer guiding decision making. We believe that the cumulative effect of these suggestions is to make DMR more and more likely and FCR an exception. This must have a compromising effect on animal welfare in the aggregate.

In addition, many IACUC decisions involve very difficult ethical questions. Indeed, weighing the potential welfare costs to research animals against possible scientific advancements is the predominant reason that the IACUC review system is in place. Therefore, going too far in streamlining the process and allowing one or very few individuals to make these determinations run the risk of eliciting insufficient deliberation on such difficult ethical questions, and potentially sacrificing animal welfare in the name of more efficient administrative practices.

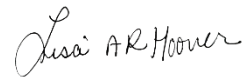
Given the stakes for the animals involved and the critical role IACUCs play in our protective framework, AWI believes that protocols should err on the side of careful review rather than administrative efficiency. We have made specific suggestions in the text above, but at a minimum **we would suggest that the proposal avoid encouraging the use of all these “flexibilities” in any one review.** Instead, AWI **suggests that IACUCs be allowed to use one streamlining approach – such as early initiation of DMR while waiting for assent – in a review, but not all of the proposed flexibilities.** This would allow flexibility and some streamlining, while not allowing the process to be so streamlined as to run the risk of becoming a “rubber stamp.”

We cannot lose sight of the central part played by IACUCs and the fact that any perceived weakening of an already less than ideal regulatory system is quite concerning and should be undertaken only if we can have complete confidence animal welfare will still be protected.

Sincerely,



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¹ See <https://olaw.nih.gov/contact-us.htm>

² See <https://olaw.nih.gov/assured/app/index.html>

³ APHIS (2022) Keeping US Agriculture Healthy for America and the World. 2022 Impact Report. Retrieved from https://www.aphis.usda.gov/publications/aphis_general/2022-impact-report.pdf

⁴ Congressional Research Service. (2022) The Animal Welfare Act: Background and Selected Issues. Retrieved from: https://www.everycrsreport.com/files/2022-07-14_R47179_2123678e15376ae95c33e9e41be2c5685f6fc574.pdf

⁵ Ibid.

⁶ Congressional Research Service. (2023) The Animal Welfare Act: Background and Selected Issues. Retrieved from <https://crsreports.congress.gov/product/pdf/R/R47179/4>

⁷ See Tutorial for PHS Policy. Retrieved from <https://olaw.nih.gov/resources/tutorial/terms.htm#3d>

⁸ Senator Robert Dole, December 18, 1985

⁹ See Animal Welfare Act & Animal Welfare Regulations, §2143 (B) (1). Retrieved from https://www.aphis.usda.gov/animal_welfare/downloads/AC_BlueBook_AWA_508_comp_version.pdf

¹⁰ See Animal Welfare Act & Animal Welfare Regulations, §2143 (B) (1). Retrieved from https://www.aphis.usda.gov/animal_welfare/downloads/AC_BlueBook_AWA_508_comp_version.pdf

¹¹ See <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-152.html>

¹² Carr, J. M. (2019) Email Obsessed: Professor Establishes Email Guidelines During Summer. *Faculty Focus*. Retrieved from <https://www.facultyfocus.com/articles/faculty-development/professor-establishes-email-guidelines-during-the-summer/>

¹³ Samuelson, W. & Zeckhauser, R. (1988) Status quo bias in decision making. *Journal of Risk and Uncertainty*. 1, pgs 7-59. Retrieved from: <https://link.springer.com/article/10.1007/BF00055564>

¹⁴ Steffel, M., Williams, E., & Tannenbaum, D. (2019) Does Changing Defaults Save Lives? Effects of Presumed Consent Organ Donation Policies. *Behavioral Science and Policy*. 5 (1). DOI: <https://doi.org/10.1177/237946151900500106>

¹⁵ See also Nouwens, M., Liccardi, I., Veale, M., Karger, D. & Kagal, L. (2020) Dark Patterns After GDPR: Scraping Consent Pop-Ups and Demonstrating Their Influence. *Conference on Human Factors in Computing Systems*. ArXiv: https://arxiv.org/pdf/2001.02479.pdf?fbclid=IwAR3T83kn_TixGxrL6SY7HYvoTR1lirBnp2UM1ISoKREWBFLQBRGA4z3P80g

¹⁶ Utz, C., Degeling, M., Fahl, S., Schaug, F., Holz, T. (2019) (Un)informed Consent: Studying GDPR Consent Notices in the Field. *2019 ACM SIGSC Conference on Computer and Communications Security*. DOI: <https://doi.org/10.1145/3319535.3354212>

¹⁷ See also Samuelson, W & Zeckhauser, R. (1988) Status Quo Bias in Decision Making. *Journal of Risk and Uncertainty*. at <https://link.springer.com/article/10.1007/BF00055564>

¹⁸ University of Colorado at Boulder; Office of Research Integrity; Institutional Animal Care and Use Committee, SOP # 4: colorado.edu/researchinnovation/sites/default/files/attached-files/sop4.pdf

¹⁹ See <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-152.html>

²⁰ The USDA, after citing the December 1985 statements by Senator Dole and the Conference Report, to its promulgation of the whistleblower protection regulation in the Animal Welfare Act, quoted in the Federal Register, March 15, 1989

²¹ See Animal Welfare Institute “In Lucrative Primate Trade, Enforcing the Law Makes Industry Cry Foul” (<https://awionline.org/awi-quarterly/fall-2023/lucrative-primate-trade-enforcing-law-makes-industry-cry-foul>) and Reuters “At Musk’s Brain-Chip Startup Animal-Testing Panel is Ride with Potential Conflicts” (<https://www.reuters.com/technology/musks-brain-chip-startup-animal-testing-panel-is-rife-with-potential-conflicts-2023-05-04/>)

²² See <https://olaw.nih.gov/policies-laws/phs-policy.htm>

²³ See “A Word from OLAW”, Nature.com: <https://www.nature.com/articles/s41684-019-0376-9>