August 1, 2022

Patricia A. Brown, VMD, MS, Director
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500,
MSC 6910
Bethesda, MD 20892

RE: Request for Information (RFI) on Flexibilities for Conducting Semiannual Animal Program Review [NOT-OD-22-114] Submitted electronically via portal and via e-mail: olaw@mail.nih.gov

Dear Dr. Brown:

The American Psychological Association (APA) represents 133,000 members, affiliates and students who serve as scientists, academics, and practitioners in health, education, government and private industry. APA has long been a strong advocate for the ethical and humane care and use of nonhuman animals in research. APA has and continues to support efforts to improve laboratory animal welfare through the implementation of policies and regulations that both maintain the integrity of the scientific research and sustain the welfare of such animals.

APA fully supports NIH’s efforts pursuant to the 21st Century Cures Act’s charge to review regulations/policies for the care and use of laboratory animals to identify areas in which administrative burden on researchers can be reduced, while ensuring the humane care and use of animals used in research. Some of the flexibilities cited here are not new. Although we appreciate NIH’s continuing support of such well-established flexibilities, we join sister scientific societies including the Council on Government Relations and the Federation of American Societies in Experimental Biology to encourage NIH to continue to think more broadly about the development of new flexibilities that it has not previously identified and announced, as the agency continues to carry out its Cures Act mandate. Additionally, we urge NIH to evaluate established flexibilities to determine if they are indeed effecting change that reduces administrative burden, and if not, how such flexibilities can be improved to achieve this result.
Specific Comments Regarding NOT-OD-22-114:

APA appreciates the opportunity to provide comments on the flexibilities outlined in NOT-OD-22-114 (in italics below). Our comments are listed below under the text of each flexibility.

**Item 1:**

The program review may be conducted at a convened IACUC meeting (e.g., in person, using teleconferencing or video conferencing) with a quorum. It is equally acceptable for the program review to be conducted by a subcommittee with no requirement for a quorum.

For example, IACUC member(s) may be assigned various program elements using the OLAW checklist and provide written reviews that can then be compiled and shared via email for the entire IACUC to consider. Members may add any comments to the compiled report.

However, a committee member or qualified individual should not be the only person assigned to review the aspects of the program for which that individual is responsible. This provides the checks and balances in the system of self-regulation and avoids biased evaluations that may arise when an individual is personally involved in the review. The PHS Policy and AWRs are silent on determining conflicts of interest regarding program review. Therefore, the IACUC may determine which situations require additional personnel, recusal, or other methods to minimize bias, based on the extent of the reviewer’s involvement and the nature of the activity.

**Comment:**

APA supports the outlined flexibilities, which also appear in the Office of Laboratory Animal Welfare’s (OLAW) December 13, 2018 webinar, “Semiannual Program Review,” given that there is language to ensure there are no conflicts of interest among the reviewers, and no IACUC member can be “involuntarily excluded from the program review.” APA appreciates NIH’s reiteration and continuing support of the flexibilities for the manner in which IACUC meetings may be conducted (e.g., in-person, teleconference, video conference), as outlined in NOT-OD-06-052, Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals (Mar. 24, 2006).

We note that semi-annual review meetings are typically scheduled at a special time (i.e., not during monthly slots for regular IACUC meetings). Reaching a quorum with busy faculty can be a challenge in the best of times. Add the complications of COVID (or similar future scenarios) and scheduling can turn into a serious problem. These changes enable institutions to perform these critical semi-annual reviews within the mandated timeframe in challenging scheduling times. One caveat, however: larger programs may need to consider this option more carefully if multiple species with varying degrees of invasiveness are present. Tracking could become unwieldy for a group of limited scope.

**Item 2:**

The PHS Policy Footnote 8 and 9 C.F.R. § 2.31(c) (3) of the AWRs allow IACUCs discretion to determine the best means of conducting the program review. For program reviews that do not involve AWA-regulated species, IACUCs may use as few as one qualified individual as an ad hoc consultant to conduct
Ad hoc consultants need not be IACUC members or institutional employees. Qualifications should include training and a working knowledge of the PHS Policy and Guide to appropriately evaluate the program and identify deficiencies and animal welfare issues.

For program reviews involving Animal Welfare Act-regulated species, the IACUC may use subcommittees of at least two IACUC members and may invite ad hoc consultants to assist IACUC members in conducting the evaluation.

Comment:
This flexibility may be more problematic. The threshold for the designation of a “qualified individual” seems low. At the very least, a scientist with IACUC experience or a research-accredited veterinarian should perform this task if it is done independently. Perhaps this flexibility was designed to accommodate smaller universities that do not use AWR species? In any case, this is an instance in which less flexibility is more desirable.

Item 3:
Standard operating procedures (SOPs) need not be reviewed every six months. IACUCs may choose the frequency and method for regular review of animal facility SOPs as part of the overall review of the animal care and use program. However, SOPs referenced in protocols should be reviewed by the IACUC at appropriate intervals, or at least once every three years according to PHS Policy IV.C.5. to ensure that they are current and accurate.

Comment:
APA is particularly supportive of removing the review of SOPs from semi-annual review. Reviewing these fixed procedures twice per year is highly redundant, and any proposed deviations from SOPs by investigators are reviewed on a case-by-case basis at monthly review by full IACUC committees. This is an area in which there is plenty of oversight, so flexibility is welcome.

Item 4: The USDA and OLAW agree that the timing of program reviews can include flexibility of within 30 calendar days of the six-month interval from the last program review, provided there is no forward drift of the date from year to year.

Comment:
APA is highly supportive of this revision. The clause about drift adds needed leniency without pace degradation.

Item 5:
IACUCs may review the entire program once every six months or on a staggered schedule. On a staggered schedule, different portions of the program are reviewed over time until the entire program
review is completed by the end of the six-month period. The 30-day flexibility also applies to each area of program review on a staggered basis.

Comment:

APA supports this option. Committees who incorporate this option into their monthly IACUC meetings can eliminate the separate biannual meeting for program review.

Item 6:

IACUCs may use an AAALAC International site visit to meet the requirements for a program review, provided it meets the requirements of the PHS Policy and AWRs. The subsequent program review must be conducted no later than six months from when the AAALAC site visit occurred with a 30-day flexibility in timing.

The IACUC must ensure the following provisions of the PHS Policy and AWRs, as applicable, are met:

For institutions covered by the PHS Policy that use the AAALAC site visit report as the semiannual report to the IO, the report must comply with all requirements in PHS Policy IV.B.3. and IV.E.1.d., which may require modifying the site visit report.

For institutions covered by AWRs, the process and report must comply with § 2.31(c)(3) of the AWRs and:

• The AAALAC International site visit should not be conducted later than the time the IACUC semiannual program review was to be conducted

• At least two members of the IACUC assisted in conducting the program review

• All members are informed of the program review to be conducted by the appointed subcommittee in sufficient time to request participation

• No IACUC member wishing to participate in any evaluation was excluded

• The report was signed by a majority of the IACUC members (individual digital signatures are acceptable)

• The program of humane care and use addresses all the required areas of the animal care and use program

• Any identified departure from the AWA Regulations and Standards includes a description of and reason for the departure

• The report distinguishes significant from minor deficiencies.

Comment:

APA supports this option for AAALAC-accredited institutions. This is a very thorough review. One caveat, however: to meet PHS requirements, two voting members of the IACUC should be part of the process to make the review official. Another note – these reviews are AAALAC contained and would not therefore be publicly available, as are the standard semi-annual reviews for USDA-covered species. We
suggest adding language to the flexibility guideline to specify that arrangements should be made to make this information available to the USDA when an AAALAC program review also serves as a semi-annual program review.

**Item 7:**

*OLAW has developed a checklist to help IACUCs conduct the program review and facility inspection. Institutions are not required to use this checklist, and it can be amended as necessary to reflect the institution’s program and needs.*

Comment:

APA has no comment to add on this item.

APA appreciates the opportunity to provide comments on flexibilities for conducting semiannual animal program reviews, given that feedback from stakeholders is necessary to the development of sound and transparent research policies. Strong oversight of animal research is critically important in a time when so many individuals doubt the need for research with nonhuman animals. Yet, we know, and regulatory agencies know, that patients and healthcare providers depend on that same research to provide understanding of, and cures for, debilitating conditions and diseases. So we must work together to design and implement ethical, fair and accountable regulatory systems. APA supports NIH’s efforts to strike the appropriate regulatory balance between burden and benefit, and we hope that these comments will assist in that endeavor. APA looks forward to future opportunities to provide feedback towards this goal.

Sincerely,

Mitch Prinstein, PhD

Chief Science Officer

American Psychological Association