



FASEB

Federation of American Societies
for Experimental Biology

Representing Over 115,000 Researchers

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July 12, 2022

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 Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide comments on the Request for Information (RFI) ([NOT-OD-22-114](#)) seeking input on flexibilities for conducting semiannual animal program review. As a coalition comprised of 28 member societies across a broad range of scientific disciplines, we applaud the National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW) and their efforts to implement flexibilities for Institutional Animal Care and Use Committees (IACUCs) conducting semiannual program reviews, an area that often contributes to institutional administrative burden. Furthermore, FASEB appreciates OLAW's collaboration with the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) to ensure updated guidance and policies are consistent across agencies, as required by the 21st Century Cures Act.

IACUCs play a fundamental role in ensuring researchers comply with federal laws and regulations while ensuring high-quality animal care and welfare. Policy flexibilities, including those for conducting semiannual program reviews, enable IACUCs to fulfill their obligations with the latitude necessary to adapt to each institution's respective needs and circumstances. In finalizing flexibility guidances, FASEB encourages OLAW to leverage the use of various communication platforms—specifically webinars and workshops for IACUCs members such as “OLAW Conversations”—to facilitate awareness and address potential areas of misunderstanding. This level of communication is particularly important as the 21st Century Cures Act implementation remains ongoing and therefore, frequent updates to agency guidance risks confusing researchers and IACUC members. Additionally, when considering future policy changes associated with administrative burden, FASEB recommends OLAW maintain active engagement with the scientific community to solicit their feedback and ensure implementation supports the collective goal to strengthen animal care standards without posing additional, unwarranted regulatory burden.

FASEB concurs with the seven flexibilities related to semiannual program review and believes their employment saves time and resources for IACUCs, permitting them to sharpen focus towards enhancing animal care.

We offer the following comments on the flexibilities below, specifically for flexibility #3.

Full members: The American Physiological Society • American Society for Biochemistry and Molecular Biology • American Society for Pharmacology and Experimental Therapeutics • American Society for Investigative Pathology • American Society for Nutrition • The American Association of Immunologists • American Association for Anatomy • Society for Developmental Biology • Association of Biomolecular Resource Facilities • The American Society for Bone and Mineral Research • American Society for Clinical Investigation • Society for the Study of Reproduction • The Endocrine Society • American College of Sports Medicine • Genetics Society of America • The Histochemical Society • Society for Glycobiology • Association for Molecular Pathology • Society for Redox Biology and Medicine • Society For Experimental Biology and Medicine • American Aging Association • Society of Toxicology • Society for Leukocyte Biology • American Federation for Medical Research • Environmental Mutagenesis and Genomics Society • Shock Society • **Associate members:** The American Society of Human Genetics • The Society for Birth Defects Research & Prevention

Flexibilities for Conducting Semiannual Program Review

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.

FASEB does not have any comments on this flexibility.

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 the program review. 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.

FASEB does not have any comments on this flexibility.

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.**

As stated in FASEB's [previous comments](#) regarding IACUC flexibilities for semiannual inspections, we appreciate OLAW's acknowledgement that IACUC review of animal facility standard operating procedures (SOPs) is not required per PHS Policy, unless specifically referenced in animal protocols. However, this task is particularly burdensome for larger institutions whose SOP manuals are often thousands of pages long. Therefore, FASEB recommends rephrasing this flexibility to emphasize that institutions are responsible for deciding the best mechanism and frequency of SOP review.

Furthermore, FASEB encourages OLAW to include language permitting institutions to review SOPs unrelated to animal welfare on a more flexible, as-needed basis. While facility resources and equipment maintenance remain vital for conducting research, the review of their SOPs is not directly relevant to animal welfare and therefore, is outside the scope of the IACUC's expertise. By distinguishing which SOPs require routine review and those permitted to follow a more flexible schedule would significantly alleviate administrative burden for IACUCs and further clarify their role in facilitating optimal animal care.

Please see suggested language below:

“Although the PHS Policy does not specifically identify the review and approval of animal facility standard operating procedures (SOPs) as a requirement for IACUCs, institutions may use their discretion to determine the frequency and method for IACUC review of these SOPs. SOPs referenced in protocols should be evaluated at least once every three years to ensure SOPs reflect best practices, per PHS Policy. All other SOP reviews—particularly those unrelated to animal care and welfare—may follow a schedule based on institutional needs.”

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.

FASEB does not have any comments on this flexibility.

- 4. 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.**

FASEB does not have any comments on this flexibility.

- 5. 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.**

FASEB does not have any comments on this flexibility.

- 6. 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.**

FASEB does not have any comments on this flexibility.

FASEB appreciates the opportunity to provide comments on flexibilities for conducting semiannual animal program reviews, as stakeholder feedback is central to developing sound and transparent research policies. We appreciate OLAW's commitment to reducing the administrative burden in animal research without compromising scientific integrity or the level of animal care and look forward to future opportunities to provide feedback towards this goal.

Sincerely,

A handwritten signature in black ink, appearing to read "Kevin C. Kregel". The signature is fluid and cursive, with the first name "Kevin" and last name "Kregel" clearly distinguishable.

Kevin C. Kregel, PhD
FASEB President

