



# FASEB

Federation of American Societies  
for Experimental Biology

*Representing Over 130,000 Researchers*

301.634.7000  
www.faseb.org

9650 Rockville Pike  
Bethesda, MD 20814

September 1, 2020

Office of Laboratory Animal Welfare (OLAW)  
National Institutes of Health (NIH)  
RKL 1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982

**RE: Request for Information (RFI) on Flexibilities for Conducting Semiannual Animal Facility Inspections [NOT-OD-20-145]**

Submitted electronically via portal and via e-mail: [olaw@mail.nih.gov](mailto: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-20-145](#)) seeking input on flexibilities for conducting semiannual animal facility inspections. As a coalition comprised of 29 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 animal facility inspections, a key area of administrative burden for investigators. Furthermore, FASEB commends OLAW for addressing the discrepancies between the United States Department of Agriculture (USDA) Animal Welfare Regulations and NIH Public Health Service (PHS) Policy concerning mechanisms by which Institutional Animal Care and Use Committees (IACUC) may conduct semiannual inspections.

Recognizing the delicate balance between animal oversight and policy harmonization with USDA Animal and Plant Health Inspection Service (APHIS), FASEB appreciates OLAW's employment of flexibilities towards IACUC facility inspections particularly in light of recent events resulting from the COVID-19 pandemic. We also thank the office's efforts to publicize this information through various communication platforms, including webinars in partnership with USDA APHIS, and we encourage continued interaction with stakeholders during this unprecedented time. To continue facilitating policy harmonization and ensure these flexibilities also extend to USDA-regulated research, FASEB encourages OLAW to reiterate that USDA APHIS concurs with this guidance within the formal document, as stated at the bottom of the Notice.

Moving forward, when addressing other areas of concern related to administrative burden in animal research—pursuant to the 21<sup>st</sup> Century Cures Act—FASEB also recommends OLAW maintain active engagement with the scientific community in discussions of suggested policy changes to ensure implementation supports the collective goal to strengthen animal care standards without posing additional, unwarranted regulatory burden.

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**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 • American Peptide Society • 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 Society for Birth Defects Research & Prevention • 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 • U. S. Human Proteome Organization • Society of Toxicology • Society for Leukocyte Biology • American Federation for Medical Research • Environmental Mutagenesis and Genomics Society **Associate members:** The American Society of Human Genetics

Although FASEB maintains the position that animal facility inspections should be reduced to an annual schedule, as outlined in our [previous statements](#) as well as the 2017 report on [Reforming Animal Research Regulations](#), we recognize this requires Congressional action to amend the Animal Welfare Act and Health Research Extension Act. However, the flexibilities outlined in the PHS Policy provide satisfactory latitude for institutions to adapt to individual requirements and circumstances. Therefore, FASEB concurs with the ten flexibilities outlined below and believe their implementation will save time and resources, permitting researchers to sharpen focus towards enhancing animal care.

FASEB offers the following comments on specific flexibilities below.

### **Flexibilities for Conducting Semiannual Inspections**

- 1. The IACUC has discretion to determine the best means of conducting the facility inspections. This includes using qualified individuals as ad hoc consultants. For areas housing non-Animal Welfare Act (AWA)-regulated species, the IACUC may use as few as one qualified individual to conduct the inspections. However, as is always required for semiannual inspections, no IACUC member should be involuntarily excluded from the inspections, and the IACUC remains responsible for the evaluation and report to the Institutional Official (IO).**

N/A

- 2. The timing of facility inspections may extend 30 days beyond the six-month interval from the last inspection, provided there is no forward drift of the date from year to year.**

N/A

- 3. IACUCs may assign specific facility inspections to subcommittees. However, conflicts of interest should be avoided. For example, a committee member or qualified individual may not be the only person assigned to inspect areas for which that person is responsible.**

N/A

- 4. IACUCs may implement a rolling inspection process, where designated facilities are inspected over time. For example, one area or group of facilities is inspected each month until inspection of all the facilities is completed by the end of the six-month period.**

N/A

- 5. IACUCs may choose whether the inspections are unannounced or if the animal care and use personnel are notified prior to inspection. Announced visits may facilitate the inspection process by having key personnel available to answer any questions.**

N/A

- 6. Although the PHS Policy does not specifically identify the review and approval of animal facility standard operating procedures (SOPs) as a requirement for IACUCs, SOPs are frequently a component of an animal care and use program. IACUCs may choose the frequency and method for reviewing animal facility SOPs. All SOPs need not be reviewed every six months but should be reviewed on a regular basis as part of the overall review of the animal care and use program. SOPs referenced in protocols should be evaluated at least once every three years according to the PHS Policy to ensure that they are current and accurate.**

FASEB appreciates 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, considering that this task is particularly burdensome for larger institutions—whose SOP manuals are often thousands of pages long—we would appreciate if this flexibility were restated to emphasize that institutions are responsible for deciding the best mechanism for SOP review. More importantly, OLAW may want to consider highlighting that institutions are permitted to review non-animal welfare related SOPs on a more flexible schedule.

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 may follow a schedule based on institutional needs.”*

- 7. While all of the institution's animal facilities, including satellite facilities, must be inspected at least once every six months, IACUCs have discretion regarding oversight of areas used for routine weighing, dosing, immunization, or imaging, but should monitor these areas on a regular basis to effectively oversee activities at the institution.**

N/A

- 8. In some circumstances or for some areas of the program, including field study sites or high containment facilities, the IACUC may find it useful to use videos, photographs, written descriptions, or other appropriate remote methods to conduct the inspection. For example, one person that the IACUC considers qualified may provide a prerecorded or real-time virtual tour to IACUC members for areas housing non-AWA regulated species.**

N/A

- 9. IACUCs may use an AAALAC accreditation site visit as a semiannual inspection providing it meets the PHS and AWA (where applicable) requirements. All IACUC members are to be informed of the proposed semiannual facility inspection so as to have sufficient time to request participation, and no IACUC member wishing to participate in the inspection is excluded. The**

**semiannual report which is submitted to the IO must be signed by a majority of the IACUC members and include the following:**

- a. A description of the nature and extent of the institution's adherence to the PHS Policy, the Guide, and the Animal Welfare Act;**
- b. A description of and reason for each departure identified;**
- c. Deficiencies distinguished as minor or significant with a reasonable plan and schedule for correcting each deficiency; and**
- d. Any minority views.**

**The next IACUC inspection must be no later than six months plus 30 days from when the AAALAC site visit occurred.**

N/A

**10. OLAW has developed a checklist to help IACUCs conduct the Semiannual 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 need**

N/A

Sincerely,

A handwritten signature in cursive script, appearing to read "Louis B. Justement".

Louis B. Justement, PhD  
FASEB President