



October 20, 2020

Via Electronic Submission to:

<https://rfi.grants.nih.gov/?s=5ef21711bb380000b9006bf2>

**National Institutes of Health
Office of the Director**

RE: Comments Submitted in Response to Notice Number [NOT-OD-20-145](#), Request for Information

To Whom It May Concern:

The Council on Governmental Relations (COGR) is an association of 190 public and private U.S. research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions. One area of significant interest and expertise among COGR member institutions is ensuring the integrity of basic and applied animal research. This research enables fundamental knowledge that leads to new treatments and insights to improve human health.

COGR appreciates the opportunity afforded by the National Institutes of Health (NIH) to provide information in response to the July 22, 2020, *Request for Information (RFI) for Conducting Semiannual Animal Facility Inspections*, Notice Number: [NOT-OD-20-145](#) ("RFI").

The RFI lists flexibilities available to Institutional Animal Care and Use Committees (IACUCs) in conducting semiannual inspections of animal study areas and facilities and requests input on these flexibilities. This letter provides general comments on semiannual inspections and the flexibilities, followed by specific comments on four of the specified flexibilities.

General Comments on Semiannual Inspections

COGR member institutions appreciate the importance of protecting the health, safety and welfare of laboratory animals and fully support meaningful steps to achieve these goals. They also recognize that some measures may place significant burdens on researchers and research institutions but achieve little in terms of increasing research animal protections, and thus regulations must strike an appropriate balance between burdens and benefits.

The federal government also has recognized the need for striking this balance. In particular, per the requirements of the *21st Century Cures Act* ([Pub. L. 114-255](#), Dec. 13, 2016) the National Institutes of Health (NIH), U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) reviewed regulations and policies governing the care and use of laboratory animals to identify areas in which administrative burden could be reduced while ensuring appropriate protections for research integrity and research animal health, safety and welfare. The results of this review were published in the [August 2019 Report Reducing Administrative Burden for Researchers: Animal Care and Use in Research](#) (“RAB Report”). The RAB Report did not recommend any substantive changes to the requirement for semiannual inspections, noting that legislative changes would be required to enact such changes because the inspection mandates are embedded in the [Health Research Extension Act of 1985 \(HREA\)](#) and the [Animal Welfare Act of 1966 \(AWA\)](#). [RAB Report, p. 5].

COGR supports a move from semiannual inspections to annual inspections of animal research facilities. This change would substantively reduce administrative burden in this area without harming animal welfare. A great many positive changes have taken place in the conduct of animal research and the design and operation of animal research facilities since passage of the HREA 35 years ago and enactment of the AWA 54 years ago. Many facilities have replaced dispersed investigator-managed research spaces with centrally controlled and operated animal procedure rooms and housing that promote consistent oversight and enhanced compliance. Notably, the RAB Report found that between 2017-19 only 7% of self-reported instances of non-compliance were identified during semiannual inspections. [*Id.*]. Additionally, analyses of USDA inspection reports from FY 2017 and 2018 found a 50% decline in total items of noncompliance, including significant drops in the noncompliance with the AWA regulatory standards set forth at [9 CFR Chapter I, Subpart A, Part 3](#). [Bennett, B.T. & Bailey, M.R. “Taking a closer look at the USDA inspection process in 2018.” *Lab Animal* 48, 225 (2019). Available at <https://www.nature.com/articles/s41684-019-0348-0#citeas>.] Given these changes, resources expended in conducting a second round of inspections each year might be more effectively deployed through targeted risk-based post-approval monitoring visits.

COGR realizes, however, that legislative action would be required to implement a shift to annual inspections. Unless and until such legislation is enacted, COGR supports all actions by NIH, USDA and FDA that meaningfully reduce administrative burden in this area.

General Comments on Specific Flexibilities

COGR members appreciate the flexibilities listed in the RFI because they provide IACUCs with tools for allocating facility inspection duties across IACUC members and consultants, as well as allowing for some limited variability in terms of inspection timing. Many of the cited flexibilities are included in underlying regulations or policy, and some stem from official interpretation of those documents. Although these flexibilities make the inspection process somewhat less rigid, they do little to reduce the overall burden on the IACUC of performing an inspection of facilities every six months. Indeed, when the two mandated IACUC facility inspections are considered in conjunction with the annual USDA inspection of animal

facilities for species covered under the AWA, most animal facilities undergo formal, documented inspections at least three times per year.

Comments on Specific Flexibilities

COGR has no specific comments on the flexibilities outlined in items 1, 2, 4, 5, 7 and 10. Individual comments on the flexibilities set forth in items 3, 6, 8 and 9 follow:

Item 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.

Comments:

COGR agrees with the intention of this comment that persons performing IACUC inspections should not have conflicts of interest that may cloud their judgment. The provided example, however, is written so broadly that it may make it very difficult for IACUCs to form inspection teams. For instance, it could be interpreted to prevent two institutional veterinary members of the IACUC from conducting an inspection because they have responsibility for animal care across all institutional facilities. Yet veterinarians who participate in IACUC inspections often have the most knowledge about animal care and use standards and about the facilities that they inspect. COGR requests that NIH consider deleting the sentence setting forth the example, as the instruction to avoid conflicts of interest is clear as it stands.

Item 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.

Comments:

As noted in this statement, the PHS Policy does not require IACUCs to review and approve animal facility standard operating procedures (SOPs). The matter in which these SOPs are reviewed should be left to each institution's animal care and use program. The third sentence of this statement, however, causes confusion because it first states that all SOPs do not need to be reviewed every six months, but then suggests that SOPs be reviewed as a part of program review, a process that *is* required every six months. The lack of clarity in this third sentence may contribute to an unintentional and unnecessary increase, rather than decrease, in administrative burden, and COGR requests that NIH consider eliminating this sentence.

Item 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.

Comments:

The mechanisms for facilitating inspections mentioned in this flexibility are useful to IACUCs. COGR requests that NIH consider modifying this flexibility statement to make the following two points clear:

- Neither the PHS Policy nor the AWA apply to all field studies. [See, [Section A.6](#) of the [OLAW FAQs on the PHS Policy on Humane Care and Use of Laboratory Animals](#) (“OLAW PHS Policy FAQs”) and the implementing regulations for the AWA at [9 CFR Sections 1.1](#) and [2.31\(c\)\(2\)](#)].
- Semiannual inspections, *per se*, are not required under the PHS Policy for field studies. [[OLAW PHS Policy FAQs, Section E.4](#)].

Item 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 accreditation site visit occurred.

Comments:


As this flexibility notes, for institutions with AWA-regulated species to use an AAALAC accreditation as a semiannual inspection, both PHS Policy and AWA requirements must be met. Although there is overlap in some of these requirements, there are also differences. To avoid confusion, COGR requests that NIH consider including a description of the following two USDA requirements within this statement, i.e., (a) the report must comply with 9 CFR Section 2.31(c); and (b) at least two IACUC members must participate in the inspection.

Conclusion

COGR appreciates NIH's efforts to solicit stakeholder input in this area and looks forward to meaningful steps towards reducing the administrative burden of facility inspections and other areas of animal research while continuing to provide solid protections for the health, safety and welfare of animal subjects.

If you have any questions regarding these comments, please contact Kris West, Director of Research Ethics and Compliance, at kwest@cogr.edu.

Sincerely,

A handwritten signature in blue ink that reads "Wendy D. Streit". The signature is fluid and cursive, with the first and last names being more prominent than the middle initial.

Wendy D. Streit
President