

New changes to NIH Guidance on Flexibilities for Conducting Semiannual Program Review and Inspections

Fast Facts

- On March 22, 2024, the Office of the Director, National Institutes of Health issued [NOT-OD-24-076](#) “Guidance on Flexibilities for Conducting Semiannual Program Review” and [NOT-OD-24-075](#) “Guidance on Flexibilities for Conducting Semiannual Inspections of Animal Facilities”. These documents rescind information contained in NOT-OD-23-129 released June 2, 2023, and NOT-OD-21-164, released August 2, 2021.
- **Background:** These notices were to provide some flexibility when conducting semiannual program reviews. The intent was to try to reduce the administrative burden in accordance with the 21st Century Cures Act.
- **Summary:** There were two (2) changes in both notices. Both changes are limited to animal care and use programs that are USDA registered and therefore involve AWA-regulated species.

Changes incorporated in [NOT-OD-24-076](#) “Guidance on Flexibilities for Conducting Semiannual **Program Review**”.

- IACUCs may consider the following flexibilities when conducting semiannual program reviews:
 - For institutions covered by the PHS Policy, 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 requirements for a quorum. **However, for reviews of programs of humane care and use involving AWA-regulated species, the subcommittee(s) must present their findings to a convened quorum of the IACUC for approval.**
- IACUCs may use an AAALAC international site visit to meet the requirements for a program review, provided it meets requirements of the PHE Policy and AWRs. For Institutions covered by AWRs, the report must comply with 2.31c of the AWRs, including:
 - **The findings must be presented to a convened quorum of the IACUC for approval.**

Changes incorporated in [NOT-OD-24-075](#) “Guidance on Flexibilities for Conducting Semiannual **Inspections of Animal Facilities**”.

- **Flexibilities for Conducting Semiannual Inspections of Animal Facilities**
 - For AWA-regulated facilities, the IACUC may use subcommittees composed of at least two committee members and may also invite ad hoc consultants to assist in conducting the inspections. More than one subcommittee may be utilized, such that different subcommittees may inspect different areas of a research facility. However, both members of any subcommittee must each physically inspect, at least once every six months, all their designated areas of the

research facility's animal facilities, including animal study areas. ***Although subcommittees may perform the inspections, the subcommittee(s) must present their findings to a convened quorum of the IACUC for approval.***

- IACUCs may use an AAALAC International site visit to meet the requirements for an IACUC semiannual inspection, provided it meets the requirements of the PHS Policy and AWRs. The subsequent facility inspection must be conducted no later than six months from when the AAALAC site visit occurred. This inspection has the same 30-day flexibility in timing. The IACUC must ensure that the following provisions of the PHS Policy and AWRs, as applicable, are met:
 - **The findings must be *presented* to a convened quorum of the IACUC for approval.**
- **Effective Date:** The notices are effective March 22, 2024.
- **Applicability:** The notice applies to institutions with a PHS Assurance and/or those with AWA-regulated species and registered with the USDA. The changes though, **only apply** to those entities registered with the USDA and are actively working with AWRs species.

Considerations for IACUCs

- Compliance officials should ensure that the IACUC is informed of these changes and their applicability to the institution's program.
- IACUCs should review existing materials to identify where changes need to be made to reflect the new guidance.
- IACUCs should ensure that they are able to share findings with a convened quorum in a manner that allows for the timely submission of semiannual program reviews to the IO.