## **OFFICE OF RESEARCH AND DEVELOPMENT VETERANS HEALTH ADMINISTRATION**

## **Updated Regulatory Requirements Regarding IACUC Continuing Review of Protocols and Other Annual Reporting Requirements**

(Summary and Clarification by the Office of the CVMO)

Date: April 23, 2025 Guidance Document: AR2025-001

**1. Summary.** USDA released an updated rule on 11/24/21 stating that APHIS amended five requirements in three sections of the Animal Welfare Regulations. Of the five amendments, the amended section in *IACUC review of activities involving animals,* 9 CFR §2.31(d)(5), is summarized as follows: “replace continuing annual reviews of activities involving animals approved by the IACUC with reviews and approval by the IACUC at intervals not exceeding 3 years”.

**2. Background.** In November of 2021, United States Department of Agriculture’s (USDA) Animal and Plant Health Inspection Service (APHIS) announced a final rule, [AWA Research Facility Registration Updates, Reviews, and Reports](https://dvagov-my.sharepoint.com/personal/kristin_mayfield_va_gov/Documents/Documents/Updated%20Guidance%20Documents/AWA%20Research%20Facility%20Registration%20Updates%2C%20Reviews%2C%20and%20Reports), amending the Animal Welfare Act (AWA) regulations to reduce duplicative requirements and the administrative burden for research facilities while continuing to ensure humane animal care. This change was made by the USDA to more closely align with existing Office of Laboratory Animal Welfare (OLAW) regulations which require the IACUC to conduct a complete review of each previously approved, ongoing activity at least once every three years ([PHS Policy IV.C.5.](https://olaw.nih.gov/sites/default/files/PHSPolicyLabAnimals.pdf)), replacing the previous requirement of annual reviews. This rules effective date was December 27, 2021. VA policy currently requires application of USDA requirements to all VA animal use protocols, regardless of whether the species involved are regulated by USDA.

**3.** **Current Guidance Regarding IACUC Continuing Review of Protocols.** VA Directive 1200.07 and subsequent Annotations and Guidance for Implementation of VHA Directive 1200.07 further support these regulations by reiterating in Section 10.d(6) that the IACUC approval expires on the date specified by the internal VA IACUC, or at the end of the maximum period of approval (three years) allowed by PHS policy (IV.C.5, and OLAW FAQ, D.1) and the AWR (§2.31(d)(5)), whichever comes first. For the work to continue after that, the approval of the IACUC must be secured for a new protocol covering the continuation of the work, prepared on the most current version of the appropriate form. Any approval of a protocol granted by an internal VA IACUC expires no later than the third anniversary of its approval, and the work may only continue after the internal VA IACUC provides a complete review and approves another protocol to cover continuation of the work.

OLAW requires “continuing IACUC oversight of animal activities” but does not specify mechanisms or timetables for it, besides the requirement for complete review at least once every three years. This allows internal VA IACUCs the flexibility to manage continuing review of approved protocols on a case-by-case basis according to the species, procedures, and complexity of the protocols involved. The internal VA IACUC has the discretion to require continuing reviews, at any frequency and at any level of detail that it deems appropriate, in addition to the required complete review at least every three years. It is up to the internal VA IACUC to specify whether IACUC approval expires when a continuing review is due. *The Guide* (p. 33) also describes possible methods for continuing review to include “continuing protocol review; laboratory inspections (conducted either during regular facilities inspections or separately); veterinary or IACUC observation of selected procedures (post approval monitoring); observation of animals by animal care, veterinary, and IACUC staff and members; and external regulatory inspections and assessments.”

**4. Compliance with Current Guidance**. For PHS purposes, the maximum interval between IACUC approvals for an ongoing activity is three years (PHS Policy IV.C.5). There is no provision for IACUCs to grant administrative extensions of that time interval. Accordingly, a formal continuing review process using one of the two described procedures (Designated Member Review or Full Committee Review- PHS Policy IV.C.2) is required. Continuation of animal activities beyond the maximum approval period without such review would be a violation of PHS Policy and the terms and conditions of the NIH grant. The VA requires the submission of a completely new Animal Component of Research Protocol (ACORP) as part of this renewal process.

OLAW Notice NOT-OD-05-034, Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals, lists “*conduct of animal-related activities beyond the expiration date established by the IACUC (note that a complete review under IV.C is required at least once every three years)*” as an example of a reportable situation requiring prompt reporting (see Section 5 below).

**5. Non-Compliance Reporting Requirements**.

* 1. Continuation of animal activities on an expired protocol is considered non-compliance with PHS Policy. Institutions should notify OLAW of matters falling under IV.F.3 (NOT-OD-05-034), promptly (i.e., without delay). Since IV.F.3 requires a full explanation of circumstances and actions taken and the time required to fully investigate and devise corrective actions may be lengthy, OLAW recommends that an authorized institutional representative provide a preliminary report to OLAW as soon as possible and follow-up with a thorough report once action has been taken. Preliminary reports may be in the form of a fax, email, or phone call. Reports should be submitted as situations occur, and not collected and submitted in groups or with the annual report to OLAW.
	2. As continuation of animal activities on an expired protocol is considered non-compliance with PHS Policy, the IACUC must notify the VA Facility Director of the reportable incident. The VA Medical Facility Director will then notify ORO within 60 calendar days of VA medical facility personnel becoming aware of the occurrence of the event or concomitantly with any notification of the event sent to NIH-OLAW, whichever is sooner. (VHA Directive 1058, 3.d(3)(4)).
	3. AAALAC International Rules of Accreditation specify that animal use not approved by the IACUC or comparable oversight body are to be reported to AAALAC International in the next Annual Report.
	4. If the VA IACUC specifies a review process *less* than the required triennial (de novo) review, and the protocol work extends beyond this internal required review date, reporting to external authorities is not required by Federal regulations.

*Note: If the PHS Assurance associated with the local IACUC indicates more frequent review requirements and this schedule was not adhered to, then this failure to adhere to the Assurance would be reportable to OLAW.*

As described in VA Directive 1200.07.10.d.(6), not granting approval to another protocol before the three-year expiration of the previous one is not itself noncompliance, but none of the work described in the protocol may be performed after it expires, until the IACUC approves another protocol that covers that work. Any work done with animals without IACUC approval is noncompliant and must be reported to regulatory authorities as described above.

**6. Additional Annual Reporting Requirements:**

1. *VMU Annual Report*. The internal VA IACUC works together with their affiliates, if necessary, to collect for inclusion in the report information about any VA research with animals that was conducted during the previous federal fiscal year, October 1 to September 30. This information is submitted online on a website accessible only from within the VA network. This is due around Jan 15 of each year (the specific date is announced via emails sent to the local VA research administrators, about 2 months ahead of time).
2. *OLAW Annual Report*. The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals [IV.F.1., 2., and 4.](https://olaw.nih.gov/policies-laws/phs-policy.htm#ReportingRequirements) require that at least once every 12 months the IACUC, through the Institutional Official (IO), must report to OLAW to include the following information:
	* + 1. Any change in the institution’s accreditation status;
			2. Any change in the institution’s program of animal care and use or facilities;
			3. Any change in the IO;
			4. Any changes in the IACUC membership;
			5. The dates that the IACUC conducted its semiannual evaluations of the program and facilities; and
			6. Any minority views filed by members of the IACUC.

The Annual Report to OLAW reporting period is the Federal fiscal year, October 1 to September 30, with the Annual Report due on or before December 1 (but no earlier than September 30).

1. *AAALAC International Annual Report*. Each year in mid-December, the AAALAC International office makes available the online Annual Report form, submission of which is required in order to maintain accreditation. Each facility may choose from a variety of reporting periods (e.g., university fiscal year, calendar year, federal government fiscal year, government oversight body reporting period, etc.) as their AAALAC International reporting period as long as the period covered is continuous with previous reports (i.e., there are no gaps and all periods are covered by a report). The AAALAC International Annual Report should include:
	* + 1. Key personnel contact changes;
			2. Changes in physical areas of supporting your animal care and use;
			3. Actions taken in response to Suggestions for Improvement (SFIs);
			4. Organizational structure changes;
			5. Animal usage (can use same numbers reported to USDA but also include animal numbers for species not regulated by the USDA);
			6. Protocol violations which had the potential to compromise animal welfare;
			7. Animal use not approved by the IACUC or comparable oversight body; and
			8. Significant adverse events not previously reported as required by the Rules of Accreditation.
2. *USDA Annual Report*. Each USDA-registered research facility and Federal research facility is required by §2.36 of the Animal Welfare Act (AWA) to submit an Annual Report (APHIS Form 7023) that documents its use of animals for research, testing, teaching, experimentation, and/or surgery. USDA Animal Care maintains a system for registered Research facilities which allows them to submit their annual animal usage report and supporting documents easily and securely via a web-based portal. The reporting portal is only open from October 1st through December 31st of each year.

**5. Additional questions.** For questions on this guidance, please contact the CVMO’s Office VACVMO@va.gov. Questions related to reporting of animal welfare incidents under VHA Directive 1058 should be referred to the Research Safety and Animal Welfare team in ORO at AskORO@va.gov. Questions about the PHS Policy and the USDA AWAR should be referred to the NIH Office for Laboratory Animal Welfare and the APHIS Animal Care Office, respectively.