



Vice President for Research
Center for Comparative Medicine

Response to USDA Non-Critical Finding (INS-0001381978) – §2.31(c)(7)

Dr. Rachel Perez-Baum
Veterinary Medical Officer
USDA APHIS Animal Care

Dear Dr. Perez-Baum,

On behalf of the University of Virginia's animal research community, I would like to express our sincere appreciation to you and the USDA for your continued commitment to ensuring the highest standards of animal care and welfare in research. We fully share and uphold these values at UVA, recognizing the essential role regulatory oversight plays in advancing ethical and impactful scientific discovery for the benefit of both human and animal health.

We appreciate your thoughtful review and discussion during the July 29, 2025, inspection regarding the cited item under §2.31(c)(7), which addressed a modification to IACUC Protocol #4194 that was implemented prior to formal documentation through the Veterinary Verification and Consultation (VVC) pathway or IACUC approval.

As discussed during the inspection, the veterinary team, including clinical veterinarians and veterinary technicians, were actively involved in the entirety of this study and made the decision to withhold NSAIDs based on clinical pain assessments and integrity of the study. While the original protocol described perioperative administration of both buprenorphine and an NSAID, the veterinary team determined that buprenorphine alone was sufficient to provide effective analgesia for this surgical model.

We acknowledge that while this decision was rooted in sound clinical judgment, the change should have been formally documented through the VVC process prior to implementation. To address this, the protocol was updated immediately and approved on August 1, 2025, via the VVC mechanism, to reflect that NSAIDs are not mandatory but may be administered as needed, in consultation with the veterinary staff. This update ensures both flexibility in patient care and full alignment with IACUC policy and USDA expectations for protocol modifications.

We have reinforced training within our veterinary and IACUC administrative teams to ensure future changes, particularly those involving analgesia or other significant care components, are documented and approved prior to implementation, either through VVC or full IACUC review.

Thank you again for your guidance and partnership. We remain committed to continuous improvement and to upholding excellence in humane animal care and research integrity.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Malbrue".

Raphael A. Malbrue, DVM, MS, CertAqV, DAACLAM
Director & Attending Veterinarian
Center for Comparative Medicine
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United States Department of Agriculture
Animal and Plant Health Inspection ServiceRPEREZ-BAUM
INS-0001381978

Inspection Report

University Of Virginia
PO BOX 400301
OFFICE OF THE VICE PRESIDENT FOR RESEARCH
CHARLOTTESVILLE, VA 22904Customer ID: **495**
Certificate: **52-R-0011**
Site: 001
UNIVERSITY OF VIRGINIA

Type: ROUTINE INSPECTION

Date: 29-JUL-2025

2.31(c)(7)**Institutional Animal Care and Use Committee (IACUC).**

A modification was made to Protocol 4194 by the researcher without prior approval by the IACUC or the veterinary staff through an established Veterinary Verification and Consultation (VVC). According to the protocol, rabbits undergoing surgery will receive buprenorphine as a pain medication as well as a perioperative dose of a non-steroidal anti-inflammatory (NSAID). According to surgical records, rabbits are only receiving buprenorphine and no NSAID. According to the facility, a VVC was implemented earlier this year to remove NSAIDs from the protocol due to their potential GI side-effects in rabbits. However, rabbits underwent the protocol prior to the enactment of the VVC and still received no NSAIDs. Significant changes to a protocol such as a change to analgesia must be approved by either a veterinarian through a pre-established VVC program, or the IACUC before being implemented to ensure standard of care is being maintained. Correct by 29 August 2025 by ensuring any significant changes to animal care and use in an approved protocol are submitted to the IACUC or through an approved VVC to allow for review and approval, approval with modifications, or withholding of approval. If a change is made through a VVC, that consultation and change must be documented.

This inspection and exit interview were conducted with the Attending Veterinarian, Chief Clinical Veterinarian, and IACUC Administrator.

Additional Inspectors:

Maira Roberts, VETERINARY MEDICAL OFFICER

Prepared By: RACHEL PEREZ-BAUM
USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER

Date:
01-AUG-2025Received by Title: IACUC RepresentativeDate:
01-AUG-2025


 United States Department of Agriculture
 Animal and Plant Health Inspection Service

 Customer: 495
 Inspection Date: 29-Jul-2025

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
495	52-R-0011	001	UNIVERSITY OF VIRGINIA	29-JUL-2025

Count	Scientific Name	Common Name
000001	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000034	<i>Tupaia belangeri</i>	NORTHERN TREE SHREW
000017	<i>Oryctolagus cuniculus</i>	DOMESTIC RABBIT / EUROPEAN RABBIT
001212	<i>Microtus ochrogaster</i>	PRAIRIE VOLE
000395	<i>Zonotrichia leucophrys</i>	WHITE-CROWNED SPARROW
001659	Total	