



Inspection Report

OLD DOMINION UNIVERSITY
OFFICE OF RESEARCH, 1 OLD DOMINION UNIVERSITY
NORFOLK, VA 23529

Customer ID: **494**
Certificate: **52-R-0009**
Site: 001
OLD DOMINION UNIVERSITY

Type: ROUTINE INSPECTION
Date: 15-SEP-2021

2.31(c)(7) Direct

Institutional Animal Care and Use Committee (IACUC).

Multiple changes were made to protocol 20-013 by the investigator without notifying the attending veterinarian or the IACUC and allowing them to review the modifications. Protocol 20-013 was approved by the IACUC in June of 2020 and uses rabbits as a model to test the efficacy of drugs against chronic lung injuries. In the approved protocol, rabbits are anesthetized and an irritant is instilled into the trachea through a catheter to produce a chronic lung injury. Changes to the protocol included:

- 1) The protocol states that the rabbits will be continuously monitored post-operatively for at least four hours. It also states that the animals will be monitored continuously until they completely recover and are returned to the cage and then observed at hourly intervals until 5 pm and daily after that.
 - a. The following five rabbits have no documentation showing post-operative observation after instillation of the irritant into the trachea: ID# 20-0543, 20-0547, 20-0541, 20-0545, 20-0542.
 - b. The remaining five rabbits have no documentation of post-operative observation hourly until 5 pm after becoming sternal: ID# 20-0539, 20-0540, 20-0544, 20-0538, 20-0546.
 - c. The following four rabbits have no documentation of consistent post-operative daily observation: ID# 20-0547, 20-0546, 20-0541, 20-0545

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2) The protocol at one point indicates that rabbits will be treated post-operatively with an antibiotic (Baytril) under the skin once a day for a total of 10 days. However, in two other parts of the protocol, it indicates that the antibiotic will be administered twice a day for 10 days post-operatively. The following three rabbits did not receive antibiotics consistently in accordance with the approved protocol:

a. ID# 20-0547 underwent surgery on 9/16/20 and received antibiotics once a day on 9/16, 9/17, and 9/26. He received antibiotics twice a day on 9/21 thru 9/25. There was no record of antibiotic administration on 9/20.

b. ID# 20-0546 underwent surgery on 9/16/20 and received antibiotics once a day on 9/16 and 9/20 but twice a day on 9/21 and 9/23. However, there was no record of antibiotic administration from 9/17-9/20.

c. ID# 20-0545 underwent surgery on 9/16/20 and received antibiotics once a day on 9/16, 9/17, and 9/26. He received antibiotics twice a day on 9/21 thru 9/25. There was no record of antibiotic administration on 9/20.

3) The protocol states that intra-operative monitoring of animals (heart rate and temperature) will be performed. The following animals have no vital signs recorded during the procedure: ID# 20-0543, 20-0539, 20-0547, 20-0540, 20-0544, 20-0538, 20-0541, 20-0542.

4) The protocol indicates that rabbits will be surgically prepped on the ventral neck prior to insertion of the intratracheal catheter using a combination of 70% ethanol and betadine repeated twice. According to the internal review performed by the facility, the investigator was only prepping the area with betadine.

Making changes to a protocol without seeking IACUC review and approval does not allow the IACUC to perform adequate oversight into the use of animals for medical research.

Prior to the three rabbits used in June 2021, the PI submitted an amendment to remove the use of antibiotics, which was subsequently approved by the IACUC. Correct by 9/16/21 by allowing the IACUC to review and either approve, require

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modifications in, or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities.

2.32(b)

Personnel qualifications.

Adequate training and review of personnel qualifications is not being performed at a frequency sufficient to ensure proper care of the animals on Protocol 20-013. Medical records from ten male New Zealand white rabbits indicate multiple failures in following the written protocol, resulting in inadequate medical care. Following the unexpected deaths of four rabbits in September 2020, the institution initiated a review of the protocol along with observing procedures. The IACUC took steps to retrain the investigator prior to allowing work to continue. When work restarted in June 2021, a PAM was conducted and found evidence that the investigator left the anesthetized animal unrestrained and unattended multiple times by leaving the room. In June 2021, the investigator was permitted to continue his work under direct observation by the attending veterinarian. However, three animals in June 2021, are missing large portions of their medical records (pre-procedural exam findings and hourly observations post-procedure). The continual failures in following the written protocol indicate a personnel issue involving training.

Inadequately trained personnel can place an animal's health and welfare at risk.

Correct by 9/16/2021 by ensuring all personnel are properly trained and qualified prior to working with animals.

2.33(b)(2)

Critical

Attending veterinarian and adequate veterinary care.

A male, New Zealand white rabbit (20-0544) was found ill on a morning wellness check and subsequently died prior to receiving appropriate veterinary care. Medical records show that on 9/23/2020 at approximately 8:40 AM the rabbit was found with its head tilted back, a bluish color to its membranes, and actively having trouble breathing. The AV and PI were contacted and instructed the technician to euthanize the rabbit within the hour. Upon further examination, the facility

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noticed that the rabbit was also not using his right hind leg and it appeared abnormal (post-mortem later identified a fracture). When technicians went back to the rabbit cage at 9:48 AM to administer euthanasia solution they found the rabbit dead. Further discussion with the facility indicated that the reason for the delay by the technician was that they did not have access to euthanasia solution. Therefore, they were waiting for someone with access to the drug box to drive into the facility. The facility has since rectified the issue of drug accessibility to prevent this from occurring again. Animals having trouble breathing and with fractured limbs are in distress and require timely veterinary care. Correct by 9/16/2021 by ensuring the facility has methods to appropriately treat injuries and emergencies.

This inspection and exit interview were conducted with the IACUC Representative and Project Manager.

Additional Inspectors:

JOHN LOPINTO, VETERINARY MEDICAL OFFICER

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Species Inspected

| Cust No | Cert No | Site | Site Name | Inspection |
|---------|-----------|------|-------------------------|-------------|
| 494 | 52-R-0009 | 001 | OLD DOMINION UNIVERSITY | 15-SEP-2021 |

| Count | Scientific Name | Common Name |
|--------|-----------------|-------------|
| 000000 | NONE | NONE |
| 000000 | Total | |