United States Department of Agriculture
Animal and Plant Health Inspection Service

GHALLBERG
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Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 002
OREGON HEALTH & SCIENCE UNIV./WEST CAMPUS

Type: ROUTINE INSPECTION
Date: Mar-24-2015

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INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

A macaque was found to have necrotic lesions at three of six subcutaneous injection sites of an experimental substance. The facility 's follow-up to this incident determined that the animal received a series of six subcutaneous injections instead of a single intramuscular injection as was described in the approved protocol. An additional departure from the approved protocol was that the injection sites were not shaved. Shaving the area was to allow observation of the site post-injection.
The protocol also states that the clinical veterinary staff was to be notified when the injections were given and the IACUC was to be notified regarding the results of the study at 72 hours post-injection. A facility representative stated that the veterinary staff was not notified until 3-4 days post-injection and the IACUC was not notified until four days post-injection.
This incident resulted in injury to the animal and delay in evaluation and treatment.
The facility must ensure that from this day forward all significant changes to protocols are reviewed and approved by the IACUC prior to implementation by the Principal Investigator and research staff.

Correction date: The facility corrected the NCI prior to the time of inspection by retraining all personnel involved in the incident on the importance of following a protocol exactly, as well as on the chain of communication for working within and between departments to ensure all experimental procedures are conducted according to approved protocols.
This adverse event was self-reported to OLAW.

A high incidence of alopecia was reported on a previous inspection report. The facility's alopecia incidence was reviewed as well as supporting documentation regarding their extremely comprehensive investigation into potential causes and, therefore, remedies for the cases of alopecia at the facility.

The inspection was conducted on March 24-26, 2015, accompanied by facility representatives.

The exit briefing was conducted on March 26 with facility representatives.

Prepared By: GWYNN HALLBERG, D.V.M.
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