



### Inspection Report

University Of Washington  
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Customer ID: **1016**  
Certificate: **91-R-0001**  
Site: 001  
UNIVERSITY OF WASHINGTON

Type: FOCUSED INSPECTION  
Date: 04-APR-2017

#### 2.31(c)(7) CRITICAL

##### INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

In August 2016, the volume of blood collected from four nonhuman primates exceeded the amount approved by the Institutional Animal Care and Use Committee (IACUC) for collection in a one-week period of time during an 8-week research protocol. In addition, blood draws and sedation events occurred in an animal that had been identified as anemic; clinical signs of being pale and altered respiration were noted.

The facility self-reported that, while conducting a separate research protocol in December 2016, the volume of blood collected from one nonhuman primate very marginally exceeded the amount approved by the IACUC in the research protocol. The animal showed no clinical signs of distress, the issue was promptly reported, and staff policies were reviewed.

The research facility has thoroughly reviewed the circumstances surrounding these issues, and instituted corrective actions. The blood collection policy was comprehensively revised to prevent any future such occurrence and facility staff have been retrained. Further, the guidelines for suggested wording for protocols was extensively revised to include increased clarity in protocol descriptions to prevent errors due to potential ambiguity and misinterpretation. In addition, a standard operating procedure in the facility was modified to prevent a similar occurrence in the future. The source code of a computer program was modified to correct monitoring collected blood volumes so that maximum blood volume collected per time period (e.g. 7 or 14 days) are tracked using running timeframe (e.g. six days before and after the collection day) from a fixed calendar approach (e.g. Sunday through Monday).

Additionally, the Institutional Animal Care and Use Committee (IACUC) reviewed the events and issued letters of counsel or reprimand to the principal investigator and the senior management member of the affected facility. The IACUC conducted, and is continuing to conduct, an intensive review of the activities of that affected facility.

Blood draw schedules and maximum volumes of blood to be collected must be clearly delineated in the approved research protocol. The investigative staff must adhere to the protocol and relevant facility standard operating

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procedures, policies or guidelines to ensure approved limits are not exceeded. Adhering to these approved limits is required to ensure the health and well-being of the animals.

Correct from this time forward.

**2.33(b)(4) CRITICAL**

**ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.**

The research facility self-reported an adverse event that occurred on December 12, 2016 involving the death of a nonhuman primate. The animal was on a research protocol and died while under anesthesia related to an experimental magnetic resonance imaging (MRI) procedure.

The animal was monitored by research staff; however, no anesthetic monitoring records were maintained during this procedure. In addition, veterinary staff subsequently conducted a supervisory review of anesthetic records for MRI procedures in the last year and found the records were partially incomplete.

Prior to the inspection, the facility's supervisory staff had instituted changes in the MRI anesthetic procedures and retrained all staff to chart anesthetic events appropriately. In addition, the Institutional Animal Care and Use Committee (IACUC) has reviewed the events and issued a letter of reprimand to the affected facility. They have also taken action to ensure that supervisors provide adequate staff training and provide general oversight of these procedures.

Appropriate anesthetic monitoring of all animals is a required standard of veterinary care. These records provide the anesthetist with a visual, long term view of the anesthetic, such that subtle changes or trends are detected and corrective action can be taken promptly to assure the health of the animal.

Correct from this time forward.

This inspection and exit briefing were conducted with the facility representatives.

**Additional Inspectors**

Schnell Michael, Veterinary Medical Officer

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