

November 1, 2006

John A. Coulter
Executive Director
Health Sciences Administration
University of Washington
C314 Health Sciences Center
Box 356355
Seattle, WA 98195-6355

Dear Mr. Coulter:

The Council on Accreditation of the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC International) has reviewed the report of the recent site visit to the University of Washington, Seattle, Washington. Council commends the staff and administrative personnel for supporting a very complex program of laboratory animal care and use. Especially noteworthy were the level of veterinary leadership and care provided across campus, inclusive of the excellent medical records in centralized facilities and the well designed and maintained medical record system in the primate center; the level of expertise and dedication of the environmental enrichment staff; the administrative operations of the Institutional Animal Care and Use Committee (IACUC), as directed through Dr. Nona Phillips and her staff; the level of husbandry and maintenance of facilities at Harborview, T wing, Mercer Building, K-wing support wing, Roosevelt, and Center on Human Development and Disability (CHDD); the design and execution of the training programs; the level of expertise and dedication to the occupational health and safety program, as demonstrated by Ms. JoAnn Kauffman, COHN-S; and the level of facility maintenance and management observed within the fish facilities.

Council acknowledges receipt of your correspondence dated July 26, 2006 detailing prompt actions taken relative to concerns expressed by the site visitors during the exit briefing. Specifically, the items included: addressing specific IACUC protocol concerns, planning to formulate guidelines on animal re-use, planning to incorporate nonhuman primate psychological well-being evaluations into the medical record system, improving the mechanisms for controlled drug distribution, correcting the need for a functional cage wash egress in RR100E, and developing procedures that address the health and safety concerns associated with the transportation of animals through general public areas.

In the Council's judgment, however, some of the deficiencies noted during the site visit were sufficiently serious to merit **PROBATIONARY ACCREDITATION** of the University of Washington for a period of six months from the date of this letter. Council encourages your prompt correction of the programmatic deficiencies described below, in anticipation that Full Accreditation may be assured. Before the end of this Probationary period, a written report of actions taken to correct the programmatic deficiencies is requested. Additional improvements in the program, particularly those related to the suggestions, should be indicated also. Based on the report and a possible revisit at the University of Washington's expense, the Council will evaluate your response to determine whether it meets the AAALAC International standards set forth in the Guide for the Care and Use of Laboratory Animals (Guide), NRC 1996, and justify continuation of Full Accreditation. The Council urges your prompt attention to the following:

tel: 301.696.9626
fax: 301.696.9627

accredit@aaalac.org
www.aaalac.org

1. Although Council acknowledges the many positive aspects of the animal care and use program of the University of Washington, it is concerned that the types of deficiencies observed during the recent site visit are an indication that there is a lack of sufficient institutional support for the program. Council believes that it is the responsibility of the institution, through the Institutional Official, to provide the resources and support necessary to ensure that the recommendations of the Guide are met. The following are specific examples of Council's overarching concern:

a. Although Council acknowledges the expert administration of the IACUC and the extraordinary dedication of some IACUC members, the performance of the IACUC regarding protocol review, programmatic review, oversight of animal use activities and committee operations was not in conformance with the Guide.

1) There were several examples of protocols that were approved but contained insufficient justification for animal numbers used and a lack of detail of adverse effects in the annual protocol review form.

Council requires that the IACUC increase the intensity of protocol review

2) The following examples of inadequate programmatic and facility review were noted:

a) Serious deficiencies that had the potential to negatively impact the health, well-being, and safety of animals and humans were not being identified during the facility evaluation. These included the facility deficiencies noted below.

b) Deficiencies that were identified were not classified as significant or minor, and no time frame for corrections were detailed. For example: programmatic deficiencies, such as the one identified in the January 2006 semiannual evaluation which indicated inadequate support for environmental health and safety follow-up, were not listed as significant or minor; the significant facility concerns in the primate center were only listed as a note in the December 2005 semiannual report

Council requires that the IACUC classify facility and programmatic deficiencies as significant or minor, and provide a time frame for correction.

3) The following examples of inadequate IACUC oversight were noted:

a) The multipurpose rooms in laboratories (e.g., F410, F404, NW145 and T163A) were used regularly and frequently for both major survival surgery and non-survival rodent surgery and were approved as such by the IACUC. Those rooms did not meet the criteria in the Guide for appropriate facilities required for surgery. The surgical area was cluttered with supplies and equipment not related to the surgical program

or procedures. There was no attempt at traffic control when surgical procedures were occurring, with people present in the surgical area with no personal protective equipment (PPE) precautions taken. In addition, adequate sanitation of the space designated for operating was not possible. The Guide recommends that surgical facilities for rodents be managed to minimize contamination from other activities in the room during surgery.

- b) Numerous laboratories throughout the campus housed animals primarily for convenience. The Guide recommends that animals should be housed in suitable facilities dedicated to or assigned for that purpose and should not be housed in laboratories merely for convenience (Guide, p. 71). Several of these laboratories were identified as being noncompliant with University policies or Guide recommendations on animal housing, care and animal use (examples below).

Animals were held in conventional laboratories with standard benches, cabinets, and equipment, which made effective sanitation and vermin control difficult. In addition, environmental conditions (such as lighting, and airflow) in the laboratory housing areas were highly variable. Chemical fume hoods were frequently used to house animals in laboratories. No heating, ventilation, and air conditioning (HVAC) system performance data were provided in the Program Description for these hoods. In some labs, the certification of this equipment was overdue. In other cases, the hood fan was not turned on. Lighting should be diffused throughout an animal holding area and provide sufficient illumination for the well-being of the animals and to allow good housekeeping practices. The lighting in the chemical fume hoods and other laboratory housing areas was inadequate to meet these expectations. In addition, none of the laboratories where animals were housed had emergency power or environmental alarms.

Specific examples of these concerns included:

Room D426 – There were 27 mouse static microisolators (MI) in the fume hood, some stacked on top of each other. There was one approximately 60 watt light bulb providing illumination for the entire area. As a result, substandard lighting was provided.

Room D435 – There was a strong ammonia odor in the room.

Room J681 – There were static microisolator mouse cages so full of dirty bedding that the bedding had wicked water from water bottle, thus no water available for mice to drink (this was observed at the end of the day – after the room had been serviced for the day by animal care technicians).

Rooms J681/F451 – The areas where the carbon dioxide euthanasia apparatus was placed were inappropriate (i.e., either in public space or on the floor in front of the working door).

Room 118 Hitchcock – The rat cages were excessively soiled.

Room 102N (FIS Building) and Room RR715 – The fume hood was overdue for certification.

Room 523 Kincaid – African Clawed Frogs were not provided any form of environmental enrichment.

Room 408 – Dry ice was used for euthanasia.

Rooms BB1220/BB1428/BB1369/RR715/RR711/F562 – Isoflurane machine certification overdue or missing in numerous labs.

Council requires that animals be housed in facilities and maintained in a manner that conforms with Guide recommendations and University policy.

- 4) The participation of the nonaffiliated member of the IACUC in protocol or programmatic review process was not readily apparent and/or adequately recorded for many of the protocols or semiannual facility reviews evaluated by the site team. Chronic nonattendance by IACUC members, especially those explicitly required by Public Health Service (PHS) Policy or U.S. Department of Agriculture Animal Welfare Regulations (AWRs), implies a lack of participation in the oversight responsibilities of the IACUC.

Council requires documentation that demonstrates that the performance of the IACUC regarding protocol review, programmatic review, oversight of animal use activities and Committee operations has been brought into conformance with Guide requirements, and applicable regulations.

- b. An occupational health and safety program must be part of the overall animal care and use program with a component of the program being adequate hazard identification and risk assessment for personnel who have contact with animals or animal products. The following practices raised concerns about the institutions risk assessment and risk management practices:

- 1) At the Western Primate Facility, one hallway located outside of Rooms 124 (office), 125 (break room), and 115 (dirty cage wash) was divided by a taped line. One side of the line was considered a Biosafety Level (BSL) 2 nonhuman primate area requiring full personal protective equipment (PPE). The other side of the taped line was used by personnel to enter offices and a shared break room. No PPE was required on this side of the taped line. Personnel that were passing

through the hallway to the break room without the benefit of PPE were exposed to SHIV-infected nonhuman primates and dirty nonhuman primate cages that were transported in the same hallway. Other than a taped line on the floor demarking entrance to a BSL2 area, there was no physical separation between SHIV-infected monkeys and personnel carrying their lunches to the break area. This created the potential for humans to be exposed to the health risks associated with nonhuman primates.

- 2) At the time of the site visit, there was no pre-employment medical evaluation, or ongoing evaluations, for those employees who were subject to substantial risk in the animal care and use program, such as employees of the Department of Comparative Medicine who would be routinely exposed to allergens or ergonomic injuries. The pre-employment evaluation was made through the use of a questionnaire, with the questionnaire being repeated every three years. It was not clear that this questionnaire would elicit information about specific medical conditions that could alter an employee's risk profile, nor was it clear if working conditions that could put employees at risk were being identified and managed in a timely manner.
- 3) The level of dust/rodent dander in many of the rooms in 6th floor of the Health Sciences Building (HSB) was excessive and the excessive amounts of water on the cage wash floor created a slip hazard however these risks had not been identified (see details below c) 3,5).
- 4) Good animal management and human health require separation of animal facilities from personnel areas such as offices and conference rooms (Guide, p.71). In a number of laboratories, personnel areas (e.g., refrigerator for food, employee workstations) were immediately adjacent to and/or intermingled with animal housing and procedural areas and personal vehicles were used to transport mice. It was not clear to the site visitors that risks associated with these practices had been evaluated or practices put in place to mitigate risks.

The University must address the above mentioned concerns through either improved facility design or procedures and increase the intensity of risk evaluation and management relative to those employees who have contact with or are exposed to animals or animal by-products.

- c. Although many of the animal housing facilities were well designed and maintained, the vivarium located on 6th floor of the Health Sciences Building (HSB) and the WaNPRC located on the main campus had significant facility flaws that were not in keeping with Guide recommendations.

The following issues were identified within the 6th floor HSB:

- 1) The rooms had extreme temperature variability (room logs indicated common temperature shifts of 8°F per day) and extremes (greater than 79°F during July

and August of 2004 and 2005) that were not within Guide recommendations. In July 2005, room temperatures in three animal holding rooms in this facility reached 104 °F; resulting in the deaths of more than 500 mice. The University reported the incident to the Office of Laboratory Animal Welfare (OLAW), installed an alarm system, and high/low temperature cut off switches. In anticipation of further temperature fluctuations, the institution had also purchased portable air conditioners and space heaters.

- 2) The floor and wall surfaces were grouted tile, which was difficult to sanitize. In addition, many of the rooms had open ceilings with a convoluted system of duct work making adequate sanitization impossible. It was conveyed to the site visit team that asbestos concerns made ceiling repairs or covering of the ceiling duct work improbable.
- 3) The odor and level of dust in many of the rooms was intense, although HVAC data indicated that environmental conditions conformed with Guide recommendations. The odors/dust may reflect room overpopulation and inadequate sanitization (due to facility design) or it may reflect failing HVAC systems.
- 4) The majority of rooms within this facility were significantly overcrowded, creating the potential for worker injury and inconsistencies in environmental conditions for the animals contained within, as some animals were exposed to light, and others were pushed against the wall where little to no light or ventilation was present.
- 5) The cage wash facility had excessive amounts of moisture accumulation on the ceiling on both days it was visited. This effectively created a 'rain' environment in the cage wash, which raised concerns about slip hazards as moisture then accumulated on the floor.

Council acknowledges the resources that have been allocated in an initial effort to correct some of the significant facility deficiencies identified in the campus based WaNPRC; however, concerns remain regarding the ability to sustain an ongoing program of maintenance and repair to support an aged facility. The following issues were identified during the recent site visit:

- 1) The floors, walls and ceiling surfaces throughout the facility were either severely compromised (peeled paint, chipped floors, missing tiles, unsealed flooring) or did not conform with Guide recommendations. Tile floors, walls, and wood doors were not able to support adequate sanitation. Chips or holes and peeled paint in floor, wall coverings, and door coverings can harbor pathogens. This may have been illustrated in recent years by several severe outbreaks of diarrhea in a stable colony of nonhuman primates in the RRwing.

- 2) In the cage wash area in the WaNPRC basement (1/1063), the single door rack washer was discharging considerable heat and steam which was not adequately dispersed by the area's ventilation system. The IACUC had identified the problem, but no correction had occurred. Council acknowledges that a grant has been submitted to provide the funds needed to correct this issue; however, the University had no plans in place to provide the funds should the grant not be funded.
- 3) The cage wash in RR wing was designed such that clean and dirty cage processing was separated only by a line on the floor with dirty caging only a few inches from clean, stored caging.
- 4) Some of the animal housing rooms were designed in a manner that prevented staff from providing the appropriate environmental enrichment such as the optimal larger caging, or activity caging.
- 5) The primate center had no mechanism in place for alerting key staff members and eliciting a response if there was an HVAC failure.
- 6) The facility lacked adequate storage space, with the result that cages were stored inappropriately in hallways.

These two facilities must be brought into conformance with Guide standards. In addition, the University must formulate, and then communicate to Council, a mechanism that ensures that all animal housing facilities are fiscally supported at a level sufficient for Guide animal housing standards to be consistently maintained.

- d. There was no after hours mechanism for monitoring heating, ventilation, and air conditioning system performance in Guthrie, Hitchcock, Kincaid, Fish Teaching Research Facilities (as well as the campus based WaNPRC mentioned above) and alerting personnel to malfunctions. In order to minimize risk to animal health and control variables that might confound research and testing, a process whereby appropriate personnel are notified when environmental variables fall outside recommended ranges must be implemented.

In addition to the correction of the specific items listed above, Council requires assurance that the Institutional Official will be provided with the necessary resources required to sustain both the program and the facility infrastructure of an animal care and use program that is able to maintain ongoing conformance with Guide recommendations.

The Council on Accreditation has concluded that correction of the problem areas listed above is essential to maintaining AAALAC International accreditation. In addition, the Council offers the following suggestions to improve further the animal care program:

1. Although the WaNPRC had defined that all nonhuman primates should be pair housed unless scientifically, behaviorally or medically justified otherwise, several of the monkeys housed on

the central campus were not afforded that opportunity due to a lack of caging. Council acknowledges that a grant has been submitted requesting the additional caging necessary, but suggests that the institution develop a plan for ensuring enough cages are available to support the policy of pair housing for nonhuman primates in the event the grant is not adequately funded.

2. Although the IACUC was duly constituted, Council is concerned that the Committee's approach to protocol and programmatic review is not in keeping with the intent of the AWRs or PHS Policy. The following are examples:
 - a) Out of approximately 250 new/renewed protocols submitted each year, approximately 1-3% of the protocols were brought up for full Committee review. Providing designated review to complex, sensitive protocols precludes the gathering of opinions and knowledge through effective Committee member interactions which likely contributed to the number of protocols that had not been adequately deliberated on less-invasive procedures or for the availability or appropriateness of other species.
 - b) The vast majority of protocols were reviewed by four permanent designated reviewers. Of these individuals, 3.5 were funded through the Office of Animal Welfare with three of those members having performance evaluations made by the Director of the University's Office of Animal Welfare. Given their salary source, these reviewers could be perceived as having a conflict of interest impeding their ability to perform unbiased protocol reviews. In addition, while the four reviewers were well trained, this practice raises a concern about the involvement of the IACUC in total.
 - c) Minutes of the IACUC meetings did not reflect actual content of discussions regarding full Committee reviews of protocols or programmatic deficiencies. The minutes should, at a minimum, include a summary of the key points discussed prior to the Committee's decision and report actual controversies and debate by the IACUC regarding protocol review or other IACUC issues considered by the Committee, rather than just stating that ".....there was discussion."

Council suggests that the University evaluate the Committee's approach to protocol and programmatic review to ensure that Committee is operating in the manner consistent with the intent of the AWRs and PHS Policy.

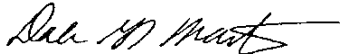
For your reference, the following statement is excerpted from the AAALAC International Rules of Accreditation:

Accreditation may be revoked by AAALAC International at any time for due cause. A previously accredited unit cannot be reverted to Provisional Status. In lieu thereof, the Council may advise an accredited unit of proposed reasons for revoking accreditation, that it has been placed on Probation and that if the specific deficiencies are not corrected within a specific period at the discretion of the Council, not to exceed twelve (12) months, accreditation will be revoked.... Notice of Probation shall be made known only to the unit and to AAALAC International.

John A. Coulter
November 1, 2006
Page 9

Please be advised that Probationary Accreditation is awarded in instances where the site visit and peer review reveal that serious but correctable deficiencies have developed in a previously Fully Accredited program. Probationary Accreditation is granted to allow time to correct deficiencies while maintaining AAALAC International accreditation. Council encourages your prompt attention to this matter and advising AAALAC International accordingly. In the interim, AAALAC International expects to be apprised in a timely manner of significant programmatic changes or concerns should they occur.

Sincerely,



Dale G. Martin, D.V.M., Ph.D.
President, Council on Accreditation

DGM:cmw
000523

cc: Thea Brabb, D.V.M., Attending Veterinarian, Clinical Associate Professor
Nona Phillips, Ph.D., Director, Office of Animal Welfare