Post-Approval Monitoring Policy
Non-Arms-Length-Managed Animal Holding Areas Certification

Approved: March 8, 2012
Revision: September 12, 2012

Goal

The Animal Use Subcommittee's (AUS) CCAC-mandated Post-Approval Monitoring (PAM) policy, developed in conjunction with Western's research community, provides the roadmap for ensuring appropriate animal care and use oversight at Western and its affiliates in compliance with national, provincial and institutional policies.   The *Post-Approval Monitoring Policy- Non-Arms-Length-Managed Animal Holding Areas Certification,* one component of the AUS's PAM policy, will provide one venue for ensuring that researchers and their staff are conducting animal-related activities in accordance with their respective approved *Animal Use* Protocols *(AUPs)* and in compliance with applicable regulations.

The primary objective of this policy is to establish a yearly certification process for holding and/or housing of live animals within non-arms-length-managed (NALM) areas.

Scope

This policy applies to all research groups intending to and/or actively holding animals, including overnight housing or housing beyond 12 hours, in an area not daily overseen by a facility manager or designate that is considered to be at arm's-length from the research group.

All researchers wishing to hold/house animals within a NALM site must receive certification by the AUS in advance of initial site use as well as annual recertification. A certificate may only be renewed following a repeat inspection.

Non-compliance during the year of certification may result in revocation of the approval, and only upon successful re-inspection of the area may approval be re-instated.

Continued animal holding beyond the year of certification constitutes *Procedural Non-Compliance* and will be treated as such.

Announced NALM site visits will be conducted by an ACVS veterinarian and/or a Protocol Support Registered Lab Animal Technician (PSRLAT) using the appended *Post-Approval Monitoring Checklist*, which will be emailed to the researcher in advance of certification/recertification.

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Principal Investigators (PIs) will ensure that the person(s) handling animals in the NALM area are properly trained and listed in the approved AUP. Persons working in this area will ensure that the work is performed and documented according to the AUP and this policy.

For further detail regarding non-compliance processes, please refer to the AUS PAM Policy at
http://www.uwo.ca/animal/website/AUS/Content/PAM.pdf

Annual Certification/Recertification Process

Criteria Used for Identifying Non-Arms-Length-Managed (NALM) Animal Holding/Housing within an AUP

- All research groups intending to and/or actively holding animals in a NALM area including overnight housing or housing beyond 12 hours must receive annual certification of these areas.
- Every AUP involving NALM areas must disclose all specific locations within AUP section *11.6 Non-Managed Holding/Housing*, including appropriate justification of the intended use of the NALM area. If this justification is not included in the AUP, a *Protocol Modification* form must be submitted immediately to the AUS office via eSirius.
- Animal Use Subcommittee (AUS) administrative staff will advise the Protocol Support Veterinarian (PS Vet) of any areas identified on an AUP that have not been certified within the past AUP year.

Pre-Visit Communications

- Upon identification of an area in need of initial certification or yearly re-certification, a member of the Post Approval Monitoring team will contact the Principal Investigator (PI) by email in order to arrange a mutually-convenient inspection time within a two-month window.
- If a PI designate has been identified, this individual will be copied on all correspondence.
- If the research group does not respond within two weeks, a reminder email and phone call will be sent.
- If no response is received within two additional weeks, the Protocol Support Veterinarian (PS Vet) will follow-up as per the AUS PAM Policy.

NALM Site Visit

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- Within two months of first notification, an ACVS veterinarian and/or PSRLAT will meet with the research group directly involved in animal care and use associated with the NALM site at a pre-determined date/time.
- Dialogue between the research group and veterinarian/PSRLAT pertaining to the NALM site and related AUP will be undertaken.
- Accompanied by research staff, the PS Vet and/or PSRLAT will tour and assess the area using the criteria within the appended *PAM Checklist.*

Post-Site Visit Follow-Up

- The PI will receive a post-site-visit itemized follow-up report, including a copy of the *PAM Checklist* assessment, via email within two weeks of visitation that will provide feedback on the visit as well as 'next steps' pertaining to any outstanding compliance concerns.
- Upon satisfactory inspection the PS Vet will, on behalf of the AUS, issue a *NALM Certificate of Approval* for a defined period not to exceed one year.
- Western's Occupational Health and Safety officer(s) will also be apprised of inspections.

At all times, ACVS Veterinarians and Technicians will endeavor to sustain and facilitate research through a collegial and supportive approach.

Animal Use Subcommittee
Western University
Non-Arms-Length-Managed (NALM) Facilities Checklist

Certification Date:	
AUP #s:	
Species:	
PI Name(s):	
Site Area Visited:	
Is breeding conducted in this area? □Yes □ No	

				Animal Ordering and Tracking
1.	Y	N	N/A	Are animals ordered centrally through ACVS, VRL or St. Joseph's Facility Managers?
2.	Y	N	N/A	Are animal numbers tracked from arrival to disposal?
3.	Y	N	N/A	Are logs of deaths maintained and ACVS Vets notified?
Comments:				

				Physical Spaces Suitability for Stated Purpose
1.	Y	N	N/A	Is there sufficient space for the stated purpose? List purpose in comments
2.	Y	N	N/A	Are there dedicated spaces available for certain procedures such as surgery?
3.	Y	N	N/A	Are there appropriate areas for storage of related equipment?
4.	Y	N	N/A	Are the necessary support equipment present (surgery prep, heat source, etc.)?
5.	Y	N	N/A	Has someone been identified as being responsible for the area and its cleanliness and maintenance? Is this info posted in or outside the room? List personnel in comments

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Comments:					
**Environmental Monitoring**					
6.	Y	N	N/A	Can temperature be monitored?	Temperature
7.	Y	N	N/A	Are necessary temperature monitoring devices present?	
8.	Y	N	N/A	Frequency of monitoring?	
9.	Y	N	N/A	Who monitors /maintains logs? List personnel in comments	
10.	Y	N	N/A	Are the parameters currently adequate M (22-25) R (20-25)?	
11.	Y	N	N/A	Can the air changes be monitored?	Ventilation
12.	Y	N	N/A	Are they appropriate? M(8-12 ventilation changes/hr) R(10-20)	
13.	Y	N	N/A	Are survival surgeries conducted in a stream of filtered air?	
14.	Y	N	N/A	Can humidity be monitored?	Humidity
15.	Y	N	N/A	Are the appropriate monitoring devices present?	
16.	Y	N	N/A	Frequency of monitoring?	
17.	Y	N	N/A	Who monitors/maintains logs? List personnel in comments	
18.	Y	N	N/A	Are the parameters appropriate M(50-70%) R(50-55%)	
19.	Y	N	N/A	Is the noise level appropriate for the species?	Noise
20.	Y	N	N/A	Photoperiod- Is it appropriate? List photoperiod in comments	Light

21.	Y	N	N/A	How do you confirm the lights are off?	
22.	Y	N	N/A	Is the light intensity within acceptable guidelines?	

Comments:

				Husbandry

23.	Y	N	N/A	Are the records of animal husbandry maintained? Daily observations recorded, including weekends and holidays?
24.	Y	N	N/A	Cage, bottle and other equipment cleaning procedures?
25.	Y	N	N/A	Is there a bedding change station?
26.	Y	N	N/A	General organization and cleanliness?
27.	Y	N	N/A	Are appropriate SOPs in place?
28.	Y	N	N/A	Is there a system for recording and notifying ACVS of sick animals and mortalities?
29.	Y	N	N/A	Is signage posted where appropriate, i.e. feeding schedule, observation schedule, endpoints etc.?
30.	Y	N	N/A	Waste disposal and vermin control in place?
31.	Y	N	N/A	Storage facilities (appropriate storage of bedding, food etc.)?
32.	Y	N	N/A	Are the milling dates on the food?
33.	Y	N	N/A	Are the surfaces sanitizable? (materials/finishes should be durable)

Non-Arms-Length-Managed (NALM) Facilities Checklist

Comments:				

				Animal & Human Safety
34.	Y	N	N/A	• Are there human safety concerns with the physical structure? • Exposed wires (unprotected electrical fixtures), slippery floors, and leaks? • Are appropriate notices and signs in place?
35.	Y	N	N/A	Are there animal health hazards associated with the physical structure?
36.	Y	N	N/A	Mechanisms for storing/limiting access to controlled substances?
37.	Y	N	N/A	Is a crisis plan in place appropriate to the purpose of the room?
38.	Y	N	N/A	• Is any PPE required for working with the animals? • Is a process in place to identify the necessary PPE? • Is it clearly identified who is to provide the PPE and how to contact them if staff requires PPE?
39.	Y	N	N/A	• Are general laboratory procedures being followed? • No eating or drinking? • Lab coats and gloves being worn at all times in the work area unless the protocol specifically describes the appropriate PPE?
Comments:				

				Security
40.	Y	N	N/A	• How is access limited to authorized personnel? • Is there protection from unauthorized personnel in place?
41.	Y	N	N/A	Who controls access?
42.	Y	N	N/A	Is the area out of direct sight from the general public?

Comments:

Overall Comments: