

Policy: Non-Arms-Length Managed (NALM) Sites

Category: Post Approval Monitoring

Subject: Animal Care Committee (ACC) obligations to ensure appropriate oversight of non-arms-length-managed sites for ACC approved animal-based science within the Western community.

Approving Authority: University Council on Animal Care

Responsible Office: Continuing Care Team

Related Procedures: Procedures for NALM Site Certification

Effective Date: 07OCT2015

Previous Approval Date: 04OCT2012

Purpose

To establish a framework for ensuring appropriate ACC oversight and Principal Investigator (PI) use of holding and/or housing animals within non-arms-length-managed (NALM) sites.

Rationale

CCAC's policy statement for senior administrators responsible for animal care and use programs states that the Animal Care Committee (ACC), animal users, veterinarians, animal care staff and the senior administrator share in the responsibility to ensure that *'animal care and use takes place in practice according to ACC decisions and institutional and CCAC standards.'* Therefore, Animal Care Committees are directly responsible for administering a post approval monitoring program that ensures animal-based science *'practice takes place as approved in principle.'*¹

For areas where animals are housed beyond 72 hours and animal care is not daily undertaken by individuals considered to be arms-length from the research undertaken therein, the ACC has an obligation to regularly assess and approve the continued use of these sites to ensure alignment with ACC, institutional and CCAC standards.

Scope

This policy applies to all NALM sites within which animal holding or housing exceeds 72 hours, including overnight housing, in an area not daily overseen by an animal care facility supervisor or designate who is considered to be at arm's-length from the research group.

ACC certification of non-arms-length sites encompasses annual site assessments focused on the macro environment, animal housing and husbandry, procurement, animal health/procedural record-keeping, and related documentation.

¹ Canadian Council on Animal Care. *Policy statement for senior administrators responsible for animal care and use programs* 5.8 P.6

Policy

Principal Investigators (PIs) must disclose all intended animal holding and/or housing beyond 72 hours within a non-arms-length-managed (NALM) site to the Animal Care Committee (ACC) within an approved Animal Use Protocol.

In advance of initial animal holding or housing beyond 72 hours, NALM sites must be assessed by ACC designates and receive certification from the ACC.

NALM sites must undergo annual recertification through reassessment and review by the ACC, or its designates.

The ACC (or designates) and PIs and their staffs must work in a timely and collegial manner to schedule, undertake and follow-up on NALM site assessments.

Assessment documentation must be forwarded to the PI associated with the NALM site in advance of certification/recertification, and following assessment forwarded in a timely manner to the ACC for review and approval.

NALM site approval certificates must be awarded to the site following ACC approval of the NALM site.

Persons working with animals in NALM sites must ensure that the work is performed and documented according to the AUP and all institutional post-approval monitoring policies, including but not limited to:

- MAPP 7.15 – Post Approval Monitoring Program
- Sick animal response must be undertaken in accordance with the *Sick Animal Response Policy*.
- Animal procurement must be undertaken in accordance with the *Animal Procurement Policy*.
- Animal-based science record-keeping must be undertaken in accordance with the *Animal Care and Use Records Policy*.

Non-compliance identified by the ACC may result in revocation of a NALM site certification. In this instance the NALM site must be reassessed and recertified prior to reinstatement of animal holding and/or housing in this area.

PI appeals regarding loss of certification status must be forwarded to “ACC Executive Team.”

Concerns identified during a NALM assessment that cannot be readily resolved by accountable parties must be forwarded through the *Concerns Identification, Project Refinement and Corrective Response* process.

Concern regarding animal holding and/or housing beyond 72 hours in NALM sites without up-to-date ACC certification must be forwarded through the *Concerns Identification, Project Refinement and Corrective Response* process.

NALM sites must be visited with a frequency proportional to the risk to animal health and welfare according to the *Continuing Care Visits and Facilitation Policy*.

NALM site representatives must participate regularly in Citywide Facility Managers meetings.

NALM site representatives must submit monthly facility update reports to the ACC.

NALM site supervisors must report and be accountable to the ACVS Director for animal health and welfare related matters.

Definitions

- **Animal Use Protocol (AUP)** – The ACC’s mandatory animal ethics form that contains details of a AUP holder’s intended live vertebrate animal care and use, which must be reviewed and approved by the ACC in advance of animal-based science or public viewing of displayed animals.
- **Accountable Parties** – Individuals directly responsible for undertaking animal-based science within NALM sites: PI and PI staff, ACC designates involved in NALM site assessments.
- **Animal Care Committee (ACC)** – A subcommittee of the University Council on Animal Care; the institutional animal care committee “responsible for overseeing all aspects of animal care and use and for working with animal users, animal care personnel and the institutional administration”; responsible to ensure animal ethics and care for animal-based science and animal displays directly associated with Western’s Research Community is in accordance with all regulatory and institutional policies and guidelines.
- **ACC Executive Team** - A subset of the ACC tasked with performing preliminary assessments of concerns and related evidence brought forward to the ACC; developing recommendations for Project Refinements and Action Plans; and assigning a specific PI Rep to incidents as they arise. This subset must include at least one ACC and ACVS leader, an ACVS veterinarian, ACC Community Rep, an ACC Coordinator, and an experienced animal-based scientist on the ACC, if not represented by the ACC leader.
- **CCAC** – The Canadian Council on Animal Care is a not-for-profit organization, created in 1968 to oversee the ethical use and care of animals in science (research, teaching and testing) throughout Canada.
- **Concerns** – Anything raised to any member regarding animal health and/or welfare, human safety, and AUP-related issues. Concerns will be reviewed by an ACC Executive Team, as appropriate. Concerns will be communicated to the PI before they are classified as either incidents or non-compliance.
- **Designate** – An individual who is adequately trained and appropriately experienced with the animals under his/her care/oversight, and who is authorized to act on behalf of either the ACC, VP Research, ACVS Director, ACVS Veterinarian, a Principal Investigator, or a Facility Supervisor.
- **NALM Site** – A macro environment where animals are housed beyond 72 hours that is not daily overseen by a facility manager or designate considered to be at arm’s-length from the research group and where animals may live out their experimental life at that site. Animals may or may not be procured directly into the site. NALM sites are primarily assessed for animal procurement, housing suitability, and appropriate husbandry practices. NALM sites do not normally include procedure areas or < 72 hour holding locations. Based upon potential risk to animal health and welfare, other areas not conforming to this definition may be identified by the ACC as NALM sites.
- **Non-Arms-Length-Managed (NALM) Site Assessment** – Annual, announced and documented evaluation of a NALM site using standardized ACC approved criteria performed by designates of the ACC and involving related PIs and their staffs. The assessment is documented using a checklist, which is disclosed to the PI and the ACC.
- **NALM Site Certificate** – A document confirming ACC approval of a NALM site that must be renewed annually. Certificates will be distributed in the name of the PI using the NALM site; therefore, multiple certificates may be issued for one NALM site.
- **NALM Site Certification** – Approval by the ACC to house or hold animals in NALM sites beyond following ACC review and approval of the associated AUP(s) and NALM assessment. Certification must be reviewed by the ACC, or its designate(s) annually in order to be maintained.
- **Principal Investigator (PI)** – A scientist responsible for undertaking animal-based science in alignment with an approved Animal Use Protocol and current veterinary standards of animal care.
- **UCAC** – Western’s Senate committee ultimately responsible for the Animal Ethics and Care program directly associated with Western’s Research Community.
- **Western’s Research Community** – Institutions and their departments involving animal-based scientists having *Animal Use Protocols* under the jurisdiction of Western’s Animal Care Committee.

Roles and Responsibilities

All stakeholders are expected to demonstrate collaborative, collegial communications and commitment to act in good faith.

- ACVS Veterinarian is responsible to:
 - provide day-to-day assistance and information with respect to animal care and use to scientists with animals in NALM sites in remaining compliant with approved AUPs and institutional and CCAC standards by ensuring
 - individual animal users are comfortable handling animals and carrying out procedures successfully, and that they are able to do so in appropriate conditions
 - act as a designate of the ACC as outlined by this policy
 - advise the ACC of current veterinary and CCAC standards regarding macro environments and husbandry
 - inform the ACC of any animal health and welfare concerns that are not readily resolved through work directly with the PI and PI staff

- ACC is responsible to:
 - establish and maintain NALM site assessment criteria that align with CCAC and institutional standards
 - appoint designates to perform NALM site assessments and act as liaisons between the ACC and the PI wishing to use NALM sites
 - review NALM site assessments in a timely manner
 - determine NALM site approval status for each assessment
 - promptly address concerns with animal-based science within NALM sites brought to its attention

- ACC Designates are responsible to:
 - act as liaisons between the ACC and the PI
 - administer communications on behalf of the ACC associated with NALM assessments and certifications
 - undertake NALM assessments in accordance with this policy and related procedures
 - provide assistance and information with respect to animal care and use to animal scientists in remaining compliant with this policy
 - forward NALM assessment documentation to the ACC requesting review
 - produce and distribute NALM site certifications
 - inform the ACC or its designates of any animal health and welfare concerns that are not readily resolved through direct work with the PI and PI staff
 - file all documentation in a readily retrievable format

- Principal Investigator (PI) is responsible to:
 - treat all animals with respect and dignity
 - be knowledgeable of and respect institutional and CCAC standards
 - undertake his/her AUP in practice as approved in principle by the ACC
 - ensure his/her research staff who directly work with animals is listed in the AUP, apprised of, appropriately trained and competently undertakes only those procedures in a manner outlined within the approved AUP



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- ensure his/her research staff who directly work with animals in the NALM site are following all PAM policies including but not limited to
 - animal procurement
 - sick animal response
 - animal care and use record-keeping
 - work with the ACC and its designates to promptly resolve any concerns brought to his/her attention

 - Principal Investigator (PI) Staff is responsible to:
 - treat all animals with respect and dignity
 - be knowledgeable of and respect institutional and CCAC standards
 - understand and exclusively follow the approved AUP(s)
 - demonstrate skill in undertaking procedures in a manner outlined within the approved AUP
 - follow all PAM policies including but not limited to
 - animal procurement
 - sick animal response
 - animal care and use record-keeping
 - work with the ACC and its designates to promptly resolve any concerns brought to his/her attention

References

- MAPP 7.12 – Policy for the Use of Animals in Research, Testing and Teaching
- MAPP 7.15 – Post Approval Monitoring Program
- Animal Care & Use Records Policy
- Continuing Care Visits and Facilitation Policy
- Animal Procurement Policy
- Sick Animal Response Policy
- Concerns Identification, Project Refinement and Corrective Response Policy
- Animals for Research Act
- CALAM Standards of Veterinary Care

Procedures for NALM Site Certification

Category: Post Approval Monitoring

Subject: Process for undertaking NALM site assessments and certification

Approving Authority: Animal Care Committee

Responsible Office: Animal Care Committee

Related Policy: Non-Arms-Length-Managed Sites

Effective Date: 10SEPT2015

Previous Approval Date: 04OCT2012

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- **NALM Site Certification** – Approval by the ACC to house or hold animals in NALM sites beyond following ACC review and approval of the associated AUP(s) and NALM assessment. Certification must be reviewed by the ACC, or its designate(s) annually in order to be maintained.
- **Principal Investigator (PI)** – A scientist responsible for undertaking animal-based science in alignment with an approved *Animal Use Protocol* and current veterinary standards of animal care.

Procedure for Identifying a NALM Site

Principal Investigators (PIs) will

- submit an *Animal Use Protocol* (if new or full renewal) or *Protocol Modification* (within-year change) form to the ACC via eSirius. AUP form to include:
 - all specific locations where animals are requested to be held or housed beyond 72 hours within the AUP section entitled, *Non-Managed Holding/Housing*
 - scientific justification for the intended use of the NALM site
 - list of PI staff to be responsible for daily monitoring within NALM site
 - list of PI staff who will perform animal procedures while within the NALM site

The ACC will

- review the NALM site details within the AUP form to determine if NALM site use is justified
- if the NALM site is ACC approved, go to Procedure for NALM Site Assessments
- evaluate PI requests for exemptions from this policy, and grant exemptions where appropriate

Procedure for NALM Site Assessments

Pre-Visit Communications

Animal Care Committee (ACC) Designates will:

- upon identification of an area in need of initial certification or yearly re-certification, contact the Principal Investigator (PI) by email in order to arrange a mutually-convenient assessment 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, send a reminder email and phone call.
- if no response is received within two additional weeks, forward the concern to the ACC as per the *Concerns Identification, Project Refinement and Corrective Response* procedures.

Principal Investigator (PI) will:

- work with the ACC designate to schedule a NALM site visit date and time that accommodates participation in the assessment by the PI and his/her staff directly involved in animal work at the NALM site

NALM Site Visit

Animal Care Committee (ACC) Designates will:

- within two months of first notification, meet with the research group directly involved in animal science associated with the NALM site at a pre-determined date/time
- dialogue with the research group regarding the NALM site and related AUPs to provide immediate feedback
- accompanied by research staff, tour and assess the area using ACC standard criteria as outlined within the NALM Site *Checklist*

Post-NALM Site Assessment Follow-Up

Animal Care Committee (ACC) Designates will:

- within one week,
 - complete the NALM Site Checklist (see below)
 - apprise Western's Animal Research Safety Consultant of any occupational health and safety concerns identified during the assessment
- within two weeks of assessment, forward to the PI a post-site-visit itemized follow-up report, including a copy of the *NALM Checklist*, via email that will provide feedback on the visit as well as 'next steps' pertaining to any outstanding concerns
- within three weeks of assessment, forward documentation to the ACC requesting review

The Animal Care Committee will:

- review all NALM assessments
- determine approval status
- communicate approval status to the ACC Designate
- follow-up on any concerns identified during the assessment, as per the Concerns Identification, Project Refinements and Corrective Response Policy and Procedures

Procedure for NALM Site Certification

ACC Designates will:

- if approved by the ACC, issue a *NALM Site Certificate of Approval* for a defined period not to exceed one year

- if not approved by the ACC, act as a liaison between the ACC and the PI, or as a support for the ACC PI Rep tasked with liaising with the PI, as directed by the ACC, in order to address outstanding issues and receive certification, as appropriate

The Principal Investigator will:

- post the NALM site certificate within clear view in the NALM site
- in the event of concerns regarding the NALM site assessment or its outcome, request a meeting with the ACC Executive Team

Certification Date:
AUP #s:
Species:
PI Name(s):
Site Area Visited:
Is breeding conducted in this area? <input type="checkbox"/> Yes <input type="checkbox"/> No

Animal Ordering and Tracking				
1.	Y	N	N/A	Are animals ordered centrally through an ACC-approved procurement administrator, <input type="checkbox"/> ACVS, <input type="checkbox"/> VRL or <input type="checkbox"/> St. Joseph's Facility Managers, <input type="checkbox"/> Other, specify: _____
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? Identify purpose _____
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 <input type="checkbox"/> surgery prep, <input type="checkbox"/> heat source, <input type="checkbox"/> Other, _____?
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 _____
Comments:				

Environmental Monitoring					
6	Y	N	N/A	Can temperature be monitored? <input type="checkbox"/> room <input type="checkbox"/> water (aquatic species)	Temperature
7	Y	N	N/A	Are necessary temperature monitoring devices present?	
8	Y	N	N/A	Frequency of monitoring, specify _____	
9	Y	N	N/A	Who monitors /maintains logs? Specify _____	
10	Y	N	N/A	Are the parameters currently adequate to the species?	
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 positive pressure space?	
14	Y	N	N/A	Can room-level 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 _____ _____	
18	Y	N	N/A	Are the parameters appropriate for the species?	
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 _____	Light
21	Y	N	N/A	How do you confirm the lights are off? - _____ _____	
22	Y	N	N/A	Is the light intensity adequate?	

Comments:				
Husbandry				
23	Y	N	N/A	Are the records of animal husbandry maintained? <input type="checkbox"/> Daily observations recorded, including weekends and holidays?
24	Y	N	N/A	<input type="checkbox"/> Cage, <input type="checkbox"/> bottle and <input type="checkbox"/> other equipment (ie. tank) cleaning procedures?
25	Y	N	N/A	Is there a bedding change station?
26	Y	N	N/A	Adequate general organization and cleanliness?
27	Y	N	N/A	Are appropriate SOPs and/or documentation in place and posted/readily available for <input type="checkbox"/> Husbandry - <input type="checkbox"/> Cleaning, <input type="checkbox"/> Feed & Watering, <input type="checkbox"/> Sick Animal Response, <input type="checkbox"/> Observation Schedule, <input type="checkbox"/> Experimental and Early Euthanasia Endpoints
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 appropriate waste disposal and vermin control in place?
30	Y	N	N/A	Are storage facilities appropriate <input type="checkbox"/> bedding, <input type="checkbox"/> food, <input type="checkbox"/> other, specify _____?
31	Y	N	N/A	Are the milling/decant dates on the food?
32	Y	N	N/A	Are the surfaces sanitizable? (materials/finishes should be durable)
Comments:				
Animal & Human Safety				
33	Y Y	N N	N/A N/A	<ul style="list-style-type: none"> • Are there human safety concerns with the physical structure? <ul style="list-style-type: none"> <input type="checkbox"/> exposed wires (unprotected electrical fixtures), <input type="checkbox"/> slippery floors, <input type="checkbox"/> leaks, <input type="checkbox"/> other, specify

				_____? <ul style="list-style-type: none"> If YES, are appropriate notices and signs in place?
34	Y	N	N/A	Are there animal health hazards associated with the physical structure? If yes, specify _____
35	Y	N	N/A	Are there proper mechanisms for storing/limiting access to controlled substances?
36	Y	N	N/A	Are crisis plans in place and appropriate to the purpose of the area? <input type="checkbox"/> area-specific <input type="checkbox"/> institutional
37	Y Y Y	N N N	N/A N/A N/A	<ul style="list-style-type: none"> Is any PPE required for working with the species? 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?
38	Y	N	N/A	<ul style="list-style-type: none"> Are general laboratory procedures being followed, <input type="checkbox"/> no eating or drinking; <input type="checkbox"/> lab coats and gloves being worn at all times in the work area unless the protocol specifically describes the appropriate PPE, other, specify _____?
Comments:				
Security				
39	Y Y	N N	N/A N/A	Is access limited to authorized personnel? <ul style="list-style-type: none"> Is there protection from unauthorized personnel in place?
40	Y	N	N/A	Who controls access? Specify: _____
41	Y	N	N/A	Is the area out of direct sight from the general public?
Comments:				

Overall Comments: