

Procedures for NALM Site Certification

Procedure Number: PROC-007

Version Number: 03

Category: Post Approval Monitoring

Subject: Process for undertaking NALM site identification, assessments and certification

Approving Authority: Animal Care Committee

Responsible Office: ACC Office

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

Approval Date: July 12, 2018

Effective Date: July 12, 2018

Revision Dates: October 4, 2012; September 10, 2015, March 8, 2018

Procedure for Identifying a NALM Site

Principal Investigators (PIs) will:

- 1) 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:
 - a) All specific locations where animals are requested to be held or housed beyond 72 hours within the AUP section entitled, *Non-Managed Holding/Housing*
 - b) Scientific justification for the intended use beyond 72 hours

The ACC or Designate(s) will:

- 2) Review the Non-Managed Holding/Housing AUP section details within the AUP form to determine if the space qualifies as a NALM site requiring annual certification, as per the NALM Sites Policy (POL-007).
 - a) If the site is ACC approved and identified as a NALM site, go to Procedure for NALM Site Assessments

Procedure for NALM Site Assessments

Pre-Visit Communications

Animal Care Committee (ACC) Designates will:

- 1) 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.
 - a) If a PI designate has been identified, this individual will be copied on all correspondence.
- 2) If the research group does not respond within two weeks, send a reminder email and phone call.

- 3) 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 (PROC-004). Principal Investigator (PI) will:
- 4) 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:

- 1) 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
- 2) Dialogue with the research group regarding the NALM site and related AUPs to provide immediate feedback
- 3) Accompanied by research staff, tour and assess the area using ACC standard criteria as outlined within the NALM Site *Checklist* (See APP 1)

Post-NALM Site Assessment Follow-Up

Animal Care Committee (ACC) Designates will:

- 1) Within one week,
 - a) complete the *NALM Site Checklist* (APP 1)
 - b) apprise Western's Animal Research Safety Consultant of any occupational health and safety concerns identified during the assessment
- 2) Within two weeks of assessment, forward to the PI a post-site-visit itemized follow-up report, including a copy of the *NALM Site Checklist* (APP 1) , via email that will provide feedback on the visit as well as 'next steps' pertaining to any outstanding concerns
- 3) Within three weeks of assessment, forward documentation to the ACC requesting review

The ACC Executive or Designate will:

- 4) Review all NALM site assessments
- 5) Determine approval status
- 6) Communicate approval status to the ACC Designate
- 7) Follow-up on any actions arising from the visit.
 - a) Concerns identified during the assessment that cannot be readily resolved by accountable parties, will be forwarded to the ACC Executive, as per the *Concerns Identification, Project Refinements and Corrective Response Policy (POL-004)* and *Procedures (PROC-004)*

Procedure for NALM Site Certification

ACC Designates will:

- 1) If approved by the ACC, issue a *NALM Site Certificate* for a defined period not to exceed one year
- 2) 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:

- 3) Post the *NALM Site Certificate* within clear view in the NALM site
- 4) In the event of concerns regarding the NALM site assessment or its outcome, request a meeting with the ACC Executive

Revision History

Version	Date	Description of Changes	Author
00	10-04-12	New procedure	LT/SG
01	09-10-15		
02	03-08-18	Updated checklist content to include SAR	SG
03	07-12-18	Updated Procedure for Identifying a NALM Site; Updated checklist to include Actionable Items, signatures, and assessment participants	SG/LT

Assessment Date: [Click here to enter a date.](#)
 PI Name(s): [Click here to enter text.](#)
 AUP #(s): [Click here to enter text.](#)
 Species: [Click here to enter text.](#)
 Site Area Visited: [Click here to enter text.](#)
 Is Breeding Conducted in this Area? [Choose an item.](#)
 Assessment Conducted by: [Click or tap here to enter text.](#)
 NALM Site Representative(s): [Click or tap here to enter text.](#)

Animal Procurement and Tracking	
Choose an item.	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: Click here to enter text.
Choose an item.	Are animal numbers tracked from arrival to disposal?
Choose an item.	Are mortality logs maintained?
Choose an item.	Are veterinarians reviewing vendor health reports for imported animals prior to delivery and examining animals upon arrival?
Choose an item.	Are monthly facility/area reports submitted to the OWL website?
Choose an item.	Are animal records maintained for the required intervals post death as per Animals for Research Act?
	Comments: Click here to enter text.
Physical Spaces Suitability for Stated Purpose	
Choose an item.	Is there sufficient space for the stated purpose? Identify Purpose: Click here to enter text.
Choose an item.	Are there dedicated spaces available for certain procedures such as surgery?
Choose an item.	Are there appropriate areas for storage of related equipment?
Choose an item.	Are the necessary support equipment present? <input type="checkbox"/> surgery prep, <input type="checkbox"/> heat source, <input type="checkbox"/> Other, specify: Click here to enter text.
Choose an item.	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: Click here to enter text.

	Comments: <i>Click here to enter text.</i>	
Environmental Monitoring		
Choose an item.	Can temperature be monitored? <input type="checkbox"/> Room <input type="checkbox"/> Water (aquatic species)	Temperature
Choose an item.	Are the appropriate temperature-monitoring devices present?	
	Frequency of monitoring? Specify: <i>Click here to enter text.</i>	
	Who monitors /maintains logs? Specify: <i>Click here to enter text.</i>	
Choose an item.	Are the parameters adequate to the species?	Ventilation
Choose an item.	Can the air changes be monitored?	
Choose an item.	Are they appropriate? M(8-12 ventilation changes/hr) R(10-20)	
Choose an item.	Are survival surgeries conducted in a positive pressure space?	
Choose an item.	Can room-level humidity be monitored?	Humidity
Choose an item.	Are the appropriate humidity monitoring devices present?	
	Frequency of humidity monitoring? <i>Click or tap here to enter text.</i>	
	Who monitors/maintains logs? List personnel: <i>Click here to enter text.</i>	
Choose an item.	Are the parameters adequate to the species?	Noise
Choose an item.	Is the noise level appropriate for the species?	
Choose an item.	Photoperiod- Is it appropriate? List photoperiod: <i>Click here to enter text.</i>	Light
	How do you confirm the lights are off? <i>Click here to enter text.</i>	
Choose an item.	Is the light intensity adequate?	
	Comments <i>Click here to enter text.</i>	
Husbandry		
Choose an item.	Are the records of animal husbandry maintained? <input type="checkbox"/> Daily observations recorded, including weekends and holidays?	

Choose an item.	<input type="checkbox"/> Cage, <input type="checkbox"/> Bottle and <input type="checkbox"/> Other Equipment (e.g. tank) cleaning procedures?
Choose an item.	Is there a bedding change station?
Choose an item.	Adequate general organization and cleanliness?
Choose an item.	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
Choose an item.	Is appropriate waste disposal and vermin control in place?
Choose an item.	Are storage facilities appropriate <input type="checkbox"/> bedding, <input type="checkbox"/> food, <input type="checkbox"/> other, specify: <i>Click here to enter text.</i>
Choose an item.	Are the milling/decant dates on the food?
Choose an item.	Are the surfaces sanitizable? (materials/finishes should be durable)
	Comments: <i>Click here to enter text.</i>
Veterinary Care	
Click here to enter text.	What species is housed here?
Choose an item.	Is this a designated or directed species according to the Sick Animal Response Policy?
Choose an item.	Do ACVS Veterinarians visit this area? How often? <i>Click here to enter text.</i>
Choose an item.	Is the Sick Animal Response (SAR) Policy and Procedures posted or readily available to research staff?
Choose an item.	Are algorithms for common health conditions with the species posted or readily available to research staff?
Choose an item.	Is there an approved SAR designate for this area?
	Please list the names of approved SAR designates <i>Click here to enter text.</i>
Choose an item.	Is the ACVS Veterinary emergency pager number posted?
Choose an item.	Is there a system in place for recording of sick and dead animals?
Choose an item.	Are ACVS Veterinarians always being notified of sick and/or dead animals?

	How are dead animals held for ACVS Veterinarians post mortem? What is the notification process? <i>Click here to enter text.</i>	
Choose an item.	Is a preventative health care program in place? Is there an SOP on this and if so, please name: <i>Click here to enter text.</i>	
Choose an item.	Is a sentinel program in place?	
Choose an item.	Are there quarantine facilities available?	
Choose an item.	Have there been any documented health concerns outside of the expected model over the last year?	
	Comments: <i>Click here to enter text.</i>	
Animal & Human Safety		
Choose an item.	Are there human safety concerns with the physical structure?	
Choose an item.	Exposed wires (unprotected electrical fixtures), slippery floors, and leaks?	Human Safety
Choose an item.	Are appropriate notices and signs in place?	
Choose an item.	Are there animal health hazards associated with the physical structure? If yes, please specify <i>Click here to enter text.</i>	
Choose an item.	Are there proper mechanisms for storing/limiting access to controlled substances?	
Choose an item.	Is a crisis plan in place appropriate to the purpose of the room? <input type="checkbox"/> area-specific <input type="checkbox"/> institutional	
Choose an item.	Is any PPE required for working with the animals?	PPE
Choose an item.	Is a process in place to identify the necessary PPE?	
Choose an item.	Is it clearly identified who is to provide the PPE and how to contact them if staff requires PPE?	

Choose an item.	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, <input type="checkbox"/> other, please specify: <i>Click or tap here to enter text.</i>
	Comments: <i>Click here to enter text.</i>
Security	
Choose an item.	Is access limited to authorized personnel?
Choose an item.	Is there protection from unauthorized personnel in place?
	Who controls access? Please Specify: <i>Click here to enter text.</i>
Choose an item.	Is the area out of direct sight from the general public?
	Comments: <i>Click here to enter text.</i>

