

**Policy: Continuing Care Visits Policy**

**Policy Number:** POL-005

**Version Number:** 01

**Category:** Post Approval Monitoring

**Subject:** Formal visits undertaken by the Animal Care Committee (ACC) and their designates to any areas in which animal-based science activities are undertaken within Western’s Research Community

**Approving Authority:** University Council on Animal Care

**Responsible Office:** Animal Care Committee (ACC) and Department of Animal Care and Veterinary Services (Institutional)

**Related Procedures:**

**Approval Date:** May 30, 2018

**Effective Date:** June 30, 2018

**Revised:** April 11, 2017

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**Purpose**

The purpose is

- to ensure appropriate onsite presence of representatives of the Animal Care Committee (ACC) and, in particular, Institutional Veterinarians, in alignment with CCAC and OMAFRA expectations and as per *MAPP 7.15 Post Approval Monitoring (PAM) Program*;
- to facilitate collaboration and transparency between Principal Investigators and their research staff, ACC members, Institutional Veterinarians, Institutional Compliance Officers, Animal Care Facility Supervisors, and their staff;
- to share best practices, and
- to enhance the outcomes for both animal health and welfare and animal-based science.

**Rationale**

Regular onsite presence facilitates a proactive rather than reactive approach to animal-based science compliance and best practices advancement and fosters a collaborative approach to CCAC- and OMAFRA-mandated post approval monitoring.

Ongoing ACC member and Institutional Veterinarian presence is required to

- facilitate effective communication; to provide meaningful support for all involved stakeholders;
- help ensure that animal environment, health and welfare issues do not arise and/or are promptly addressed;
- identify and quickly resolve Concerns, *Animal Use Protocol (AUP)* drift and/or animal facility concerns; and
- to address questions from Animal Care (AC) Facility Supervisors and Principal Investigators.

## Scope

This policy applies to all animals associated with animal-based science activities within Western's Research Community.

Continuing Care Visits, or CCVs, may include:

- ACC Site Visits
  - ACC Evaluations of Field Research
  - Facility Visits by Institutional Animal Health Professionals
  - Visits by Institutional Compliance Officers
  - ACC Directed Observations and Evaluations, and
  - AUP Visits
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## Policy

### ***Risk-Based Approach***

The ACC, with direct support from Institutional Veterinarians and their Designates, must ensure that all animal holding and use areas, including procedure rooms, are visited with a frequency proportional to risks to animal health and welfare.

The degree of risk to animal health and welfare must be outlined within the Continuing Care Visits (CCVs) Risk Analysis Record.

The Continuing Care Visits (CCV) Risk Analysis Record must be maintained by Institutional Veterinarians and the ACVS Assistant Director-Compliance Assurance, and reviewed annually by the ACC to ensure it reflects current risk levels and locations.

- The frequency of CCVs by Institutional Veterinarians and/or Institutional Compliance Officers may be determined and assigned based on the results of the annual ACC Site Visit, or any other visits described within this policy.

### ***Collaborative Approach***

Continuing Care Visits (CCVs) must be focused on discussing animal-based research in the context of current veterinary standards of care and regulatory requirements in a collegial, proactive, problem-solving manner.

Upon the request of the ACC, or its ACC Designate undertaking a CCV, PIs and AC Facility Supervisors must make themselves, or their informed designates, available to participate during CCVs associated within their area(s).

Any issues identified during CCVs must be communicated to, and resolved by accountable stakeholders in a timely manner.

Any Sick Animals identified during visits must be responded to as per the *Sick Animal Response (SAR) Policy (POL-009) and Procedures (PROC-009)*.

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Any Concerns identified during visits must be documented and forwarded to the ACC Executive for consideration as per the *Concerns Identification, Project Refinement and Corrective Response Policy (POL-004) and Procedures (PROC-004)*.

### **Documentation Requirements**

PIs and AC Facility Supervisors must ensure that Animal and Facility-Related Documentation is readily available for review by the ACC Designates undertaking CCVs.

ACC Designates responsible for undertaking CCVs must:

- maintain a CCV Log of all visits;
- document CCVs using the related CCV Report Template; and
- distribute reports to Related Stakeholders

All CCV Logs and Reports must be centrally maintained for regulatory reporting purposes; these records must be made readily available to the ACC, the Vice President (Research) and external regulators upon request.

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### **Animal Care Committee Site Visits for Animal-Based Science – Non-Field Research**

ACC Site Visits must be undertaken at minimum annually, with the exception of areas used solely for euthanasia, which must be visited at minimum every other year.

ACC Site Visits must be announced and organized in advance of the visit to ensure availability of Related Stakeholders, as applicable.

A minimum of three ACC members must participate in every ACC Site Visit to include an Institutional Veterinarian, an animal-based scientist and one other ACC member.

All ACC members must actively participate in, or at least volunteer for, a minimum of one site visit per year.

During visits, ACC Site Visit Team members must contribute evidence-based, specific feedback via verbal and written documentation using the ACC Site Visit Checklist.

An ACC Site Visit Log must be electronically filed in a central location by an ACC Designate involved in administering the ACC Site Visit program; the Log must be forwarded to the ACC Coordinator for distribution to the ACC and the ACC Executive.

- This Log should record the Recommendations and Follow-Ups from Recommendations from the ACC Site Visit Reports.

ACC Site Visit Reports must:

- be completed using the ACC Site Visit Report Template;
- include initial observations, identified commendations, and recommendations as identified on the ACC Site Visit Checklists, to include the recommended frequency of CCVs performed by Institutional Veterinarians and/or Institutional Compliance Officers for the remainder of the calendar year

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- be reviewed and approved by the ACC Site Visit Team who participated in the visit before distribution to Related Stakeholders;
  - following resolution of all recommendations, be updated and electronically filed in a centralized, easily retrievable location.

### *ACC Evaluations of Field Research*

ACC evaluations of AUPs involving Field Research must be undertaken at minimum every four years.

In the event that on-site observation by an ACC Designate is not feasible, a meeting must be arranged between the PI Field Researcher and an ACC Designate in order to determine AUP elements – procedures and/or equipment - that require evaluation.

A PI Field Researcher must provide the ACC via its Designate with video, photographic and/or other pictorial records of the following AUP elements:

- capture techniques,
- housing conditions,
- sedations/euthanasia,
- transportation,
- manual handling/restraint, and
- invasive procedures.

The ACC Designate must:

- maintain a Log for evaluations of Field Research;
- review the pictorial records provided by the PI Field Researcher and then
  - document details using an ACC-approved Field Study Evaluation Report template; distribute to Related Stakeholders; electronically file in a centralized location; and
- forward the CCV Log and Evaluation Reports to the ACC Coordinator for review by the ACC Executive.

### *Facility Visits by Institutional Animal Health Professionals*

Institutional Veterinarians must have unrestricted access to all areas where animals are held or used at all times, as per *MAPP 7.15-Post Approval Monitoring Program, III.17*.

All animal holding and use areas must be visited by an Institutional Veterinarian or designated institutional animal health professional at the frequency outlined within the Continuing Care Visits Risk Analysis Record.

The ACC Executive and/or the full ACC must provide direction and support to Institutional Veterinarians, as requested by them or required by the situation.

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### *Visits by Institutional Compliance Officers*

All animal holding and use areas must be visited by Institutional COs within their scope of accountability and at a frequency proportional to the risk to animal health and welfare guided by the Continuing Care Visits Risk Analysis Record.

Institutional Compliance Officers (COs) must:

- have ready access to all areas under their oversight, as defined by their position description;
- use an ACC approved CCV Report Template;
- during visits and prior to report submission to the ACC Designate, discuss any concerns/observations associated with the CCV with the person(s) directly responsible for the area(s); and
- maintain a CCV Log and present it for monthly review by the ACC Executive and full ACC via the ACC Coordinator.

The ACC Executive and/or the full ACC must provide direction and support to Institutional Compliance Officers, as requested by them or required by the situation.

Other stakeholders – ACVS Director, Institutional Veterinarians, ACC leaders, Animal Care Facility Supervisors - must notify Institutional Compliance Officers (CO) of any concerns arising from their visits to sites under the CO's oversight.

### *ACC Directed Observations and Evaluations*

The ACC must provide specific direction to ACC Designates regarding its observational and evaluative expectations.

For ACC Directed AUPs requiring animal health professional oversight, Institutional Veterinarians or their designates must in a timely manner:

- undertake the specific observations and/or evaluations as directed by the ACC;
- record all evaluations using an ACC-approved Report Template;
- forward Reports to the ACVS Assistant Director-Compliance Assurance; and
- maintain a Log and present it for monthly review by the ACC Executive and full ACC via the ACC Coordinator.

### ***Pilot Studies***

PIs undertaking Pilot Studies or having AUPs identified by the ACC as requiring veterinary observation and/or evaluation must provide advance notice to Institutional Veterinarians regarding the commencement of related animal procedures, and must facilitate Institutional Veterinarian observation of these procedures.

For Pilot Studies Institutional Veterinarians must:

- be actively engaged in monitoring and evaluation of experimental subjects during Pilot Studies, and in the identification and refinement of endpoints and monitoring sheets; and
- following the completion of the Pilot, provide to the ACC via an ACC Designate written veterinary evaluations of the Pilot project using an ACC-approved report template.

## ***AUP Visits***

At Annual Protocol Renewal all AUPs must be assessed with reference to the CCV Risk Analysis Record; AUPs identified as having a higher risk must receive direct follow-up by an ACC Designate.

The ACC Designate must:

- record all visits using an ACC-approved CCV Report Template;
  - forward CCV Reports to the ACVS Assistant Director-Compliance Assurance; and
  - maintain a CCV Log and present it for monthly review by the ACC Executive and full ACC via the ACC Coordinator.
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## **Roles & Responsibilities**

### **The Animal Care Committee is responsible to**

#### *General*

- ensure that all animal holding and use areas, including procedure rooms, are visited with a frequency proportional to risks to animal health and welfare
- review and approve the CCV Risk Analysis Record annually
- provide direction and support to ACC Designates who undertake CCVs, as requested by them or required by the situation
- provide direction to ACC Designates undertaking CCVs and/or reviewing CCV reports, as requested or required

#### *for ACC Site Visits*

- ensure ACC membership appropriately shares the responsibility of participating on ACC Site Visits
- ensure ACC Site Visits are undertaken in accordance with this policy and related procedures

#### *for ACC Directed Observations and Evaluations*

- ensure Pilot projects and novel or invasive animal procedures receive the appropriate level of Institutional Veterinarian oversight
- provide clear, specific direction to Institutional Veterinarians regarding evaluation expectations

### **The Animal Care Committee Executive is responsible to**

#### *General*

- review and approve CCV Report Templates used by ACC Designates undertaking CCVs
- review CCV Logs from all activities associated with this policy , and as required, review all CCV Reports associated with this policy
- provide direction and support to ACC Designates, as requested by them or required by the situation

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- respond to Concerns directed to it as per the *Concerns Identification, Project Refinement and Corrective Response Policy (POL-004) and Procedures (PROC-004)*

*for ACC Site Visits*

- ensure ACC Site Visits are undertaken at frequencies appropriate to the area and risk level
- ensure all voting ACC members actively participate in or volunteer for at least one ACC Site Visit annually
- ensure issues identified during ACC Site Visits are communicated to and resolved by accountable stakeholders in a timely manner

**ACVS Assistant Director – Compliance Assurance**

- in conjunction with other Institutional Veterinarians, ensure that the CCV Risk Analysis Record is maintained and forwarded to the ACC for review annually
- ensure the identification of AUP Visits required from review of AUPs at Annual Renewal; lead in or oversee the follow-up and reporting as per this policy
- review and communicate to the Executive any Concerns identified within either CCV Logs or Reports

**ACC Coordinator is responsible to**

- maintain a standardized, controlled, centralized electronic repository for all CCV Logs and CCV Reports
- facilitate access to CCV Logs and Reports by the ACC, the Vice President (Research), and any other regulator, e.g. CCAC, OMAFRA inspectors

**Institutional Veterinarians or their Designates are responsible to**

*General*

- in conjunction with the ACVS Assistant Director-Compliance Assurance, ensure that the CCV Risk Analysis Record is maintained and forwarded to the ACC for review annually

*for ACC Site Visits*

- provide veterinary expertise and support to involved stakeholders during and following ACC Site Visits

*for Facility Visits by Institutional Animal Health Professionals*

- undertake visits for all animal holding and use areas at the frequency outlined within the Continuing Care Visits Risk Analysis Record

*for ACC Directed Observations and Evaluations and/or AUP Visits*

- undertake observations and evaluations of animal procedures, animal user training, etc. as directed by the ACC

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- provide timely written reports arising from observations and/or evaluations to an ACC Designate using an ACC-approved template to the ACC
  - maintain related CCV Logs and forward them to the ACC Executive, as required

**Institutional Compliance Officers are responsible to**

- visit all animal holding and use areas under his/her area of accountability at a frequency proportional to the risk to animal health and welfare guided by the Continuing Care Visits Risk Analysis Record
- during visits and prior to report submission to the ACC, discuss any concerns identified with the person(s) directly responsible for the area(s)
- maintain a CCV Site Visits Log and CCV Reports; provide to the ACC Executive or designate as requested
- inform the ACC Executive of all Concerns that cannot be readily resolved as per the *Concerns Identification, Project Refinement and Corrective Response Policy (POL-004) and Procedures (PROC-004)*

**Animal Care Facility Supervisors are responsible to**

*General*

- upon the request of the ACC, or its ACC Designate undertaking a CCV, make themselves, or their informed designates, available to participate during CCVs associated with their area(s).
- ensure that Animal and Facility-Related Documentation is readily available for review by the ACC Designates undertaking Continuing Care Visits.

*for ACC Site Visits, Visits by Institutional Animal Health Professionals / Institutional Compliance Officers*

- promptly confirm availability or suggest an alternate timeframe via email for requested ACC Site Visits
- provide facility-specific entry and exit Standard Operating Procedures to ACC Site Visit Team in advance of the visit
- provide adequate PPE to Site Visit Team members
- accompany or ensure competent accompaniment for the ACC Site Visit Team to all areas under their direct supervision
- respond in a timely manner to and seek prompt resolution of all Animal Care Facility issues identified during ACC Site Visits

**Principal Investigators (PIs) are responsible to**

*General*

- upon the request of the ACC, or its ACC Designate undertaking a CCV, make themselves, or their informed designates, available to participate during CCVs associated with their area(s).
  - confirm availability or suggest an alternate timeframe via email for requested CCVs
- ensure that Animal and Facility-Related Documentation is readily available for review by the ACC Designates undertaking Continuing Care Visits.



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- direct any Concerns identified during visits that cannot be readily and appropriately resolved by accountable parties through the follow-up process to the ACC Executive for consideration as per the *Concerns Identification, Project Refinement and Corrective Response Policy and Procedures*

*for ACC Site Visits*

- be available and ensure the availability of all individuals listed on the AUP who are directly associated with current animal projects
- ensure PI staff is familiar with AUP and related SOP information
- respond in a timely manner to and seek prompt resolution of all issues pertaining to the animal project identified during ACC Site Visits

*for Institutional Animal Health Professional, ACC Leader and Institutional Compliance Officer Continuing Care Visits*

- be available and/or ensure the availability of individuals and areas listed on the AUP who are directly associated with current animal projects for requested CCVs
- focus on discussing animal-based research in the context of current veterinary standards of care in a collegial, proactive, problem-solving manner

*for ACC Directed Observations and Evaluations and AUP-Visits*

- facilitate timely Institutional Animal Health Professional observations and evaluations of animal procedures, animal user training, etc. as directed by the ACC

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## **Related Documents / References**

- ACC Site Visit Checklist
- ACC Site Visit Report
- ACC Field Study Evaluation Report
- Continuing Care Visits (CCV) Risk Analysis Record
- Continuing Care Visits (CCV) Log
- Canadian Council on Animal Care – Terms of Reference for Animal Care Committees
- Canadian Association for Laboratory Animal Medicine (CALAM) - CALAM Standards of Veterinary Care (2007)
- University Council on Animal Care
  - Concerns Identification, Project Refinement and Corrective Response Policy – POL-004
  - Sick Animal Response Policy – POL-009
- University Senate
  - MAPP 7.12 – Policy for the Use of Animals in Research, Testing and Teaching
  - MAPP 7.15 - Post Approval Monitoring Program

**Revision History**

Version	Date	Description of Changes	Author
00	04-11-17	New Policy	LT
01	05-30-2018	CCV Risk Analysis Record to receive within-year updates based upon other CCV feedback, e.g. from ACC Site Visits; remove general reporting frequency reqmt (monthly) & reqmt for Assist. Dir-Compliance Assurance to 'review' reports/logs in advance of ACC Executive Mtgs; Update CCV naming conventions (remove term CCV); Remove section for 'CCVs by ACC Leaders'; Add section for 'AUP Visits'; remove Definitions & ACC Member 'Roles & Resp'; remove R&R details for ACC Site Visit Maint from Instit. Vet role	ACVS Vets / LT