

Purpose / Scope

The threefold purpose of this policy is to:

- provide a framework for Western's Animal Care Committee (ACC) to assess concerns effectively and collegially and then respond to Incidents, Non-Compliance and Reportable Animal Welfare Incidents (RAWIs) pertaining to animal-based science;
- re-align animal procedures and related processes with the approved *Animal Use Protocol (AUP)* and/or current regulatory, veterinary, and institutional standards of animal ethics and care; and
- ensure that appropriate project refinement in response to Incidents, and action plans and/or sanctions in response to Non-Compliance and RAWIs, are promptly enacted by accountable parties.

This policy applies to animal-based science activities associated with Western and its affiliates.

Rationale

Western is obliged by its commitment to *Tri-Agency's Agreement on the Administration of Agency Grants and Awards by Research Institutions* to fully comply with Canadian Council on Animal Care (CCAC) standards. According to CCAC, Animal Care Committees are required to establish and enact a post approval monitoring program that ensures that "animal use in practice takes place as approved in principle."¹ Additionally, a framework must be established and maintained for reviewing and correcting elements of a research project that may deviate from an approved AUP and/or from current veterinary and regulatory standards of animal ethics and care.

Within Section 17 of the *Animals for Research Act*, the Animal Care Committee (ACC) is obligated to ensure compliance with Section 16; in the event of non-compliance with the Act, the ACC is required to intervene to prevent and/or alleviate animal suffering and/or unnecessary pain.² In order to fulfill its ARA mandate, the ACC has developed a system for identifying and responding to any Concerns that may impact animal health and welfare.

¹ Canadian Council on Animal Care. Policy statement for: senior administrators responsible for animal care and use programs. (2008) Sect 5.8 – ACCs and Post-approval Monitoring. Retrieved from https://www.ccac.ca/Documents/Standards/Policies/Senior_administrators.pdf

² Government of Ontario. *Animals for Research Act, R.S.*. 1990, c. A.22 Sections 16 and 17 retrieved from <https://www.ontario.ca/laws/statute/90a22#BK14>

Policy Statements

Concern Disclosure

Where reasonable and appropriate, concerned individuals must attempt to work with those responsible for live-animal activities, hereto referred to as Responsible Persons (RPs), to resolve concerns appropriately and promptly regarding a perceived departure from an approved Animal Use Protocol (AUP) or current regulatory standards that negatively impacts animal health, behaviour and/or well-being.

Responsible Persons must act collegially in good faith in order to readily and appropriately resolve concerns that have been brought to their attention.

All members of Western's Research Community must promptly notify the ACC Executive of any Concerns that are not appropriately and quickly resolved through preliminary discussions between the concerned individual and the Responsible Person (RP), and persistent breaches of compliance or threats to the health and safety of personnel or animals.

The ACC must ensure confidentiality for those who disclose their Concerns relating to an animal's health, behaviour and/or well-being in accordance with Western's *Safe Disclosure Policy* (MAPP 1.43).

All Concerns brought forward to the ACC must be based upon evidence presented to and corroborated by the ACC Executive in order to be classified.

Within 14 days of occurrence, the ACC Chair, attending veterinarian or designate must notify the Canadian Council on Animal Care (CCAC) of a reportable animal welfare incident (RAWI) – see Glossary - using the *CCAC Reportable Animal Welfare Incident Initial Notification Form* to rawi@ccac.ca. Updated information pertaining to root cause(s) and steps taken to resolve deficiencies must be relayed to CCAC using the *CCAC Reportable Animal Welfare Incident Form*.⁴

Concern Response

Where the ACC, or designate, has reason to believe that an offence has been or will be committed against section 16 of the *Animals for Research Act, R.S.O. 1990*, pertaining to unnecessary animal suffering, the ACC or designate(s) must immediately prevent, stop or alleviate that suffering.

All matters brought to the attention of the ACC Executive must be classified as an Incident, Non-Compliance, or a RAWI once substantiated through fact-finding.

The ACC Executive's degree of response to Incidents, Non-Compliance, and RAWIs must correspond to the potential impact upon an animal's health and well-being.

The ACC Executive must

- notify the RP and/or their supervisor, and the full ACC of Concerns brought to its attention and give opportunity for them to respond to the information presented; and

⁴ Canadian Council on Animal Care. (2022) Frequently Asked Questions. CCAC Reportable Animal Welfare Incidents. Retrieved from https://ccac.ca/Documents/Assessment/CCAC_frequently_asked_questions_CCAC_reportable_animal_welfare_incidents.pdf

- ensure the RP is provided with up-to-date information as it is collected by the ACC Executive with respect to the Concern with the exception of documentation that may breach confidentiality, per MAPP 1.43.

Non-Compliance and Reportable Animal Welfare Incident Classifications

For instances involving allegations of Non-Compliance and Reportable Animal Welfare Incidents, and as applicable to the situation:

- the ACC Chair and/or Institutional Veterinarian must immediately intervene to prevent and/or relieve animal suffering, as per ARA, Section 17, and promptly address persistent breaches of compliance or threats to the health and safety of personnel or animals by following this policy and associated procedures; and
- the ACC Executive must notify the full ACC, institutional senior administration and external regulators of the allegations/situation and action plans/sanctions imposed.

Breaches of compliance that cannot be corrected by the ACC and its Executive in conjunction with institutional stakeholders must be referred to the Vice President (Research) or designate.

Concern Response Documentation

A written record of all Incidents, Non-Compliance and RAWIs, related meetings, project refinements, action plans and sanctions must be documented by the ACC and made readily available to Senior Administrators and regulators, as applicable to the situation.

Notes and/or meeting minutes must be taken at all meetings associated with fact-finding, Incidents, Non-Compliance, and RAWIs and then distributed to meeting participants for review and comment.

As applicable, action plans and sanctions associated with Non-Compliance must be communicated to granting agencies via Research Western's Grants Office.

Animal Use Protocol Requirements

In response to identified project refinements associated with Incidents and/or Non-Compliance and/or RAWIs involving Animal-Based Scientists must submit a Protocol Modification form to reflect agreed-upon alterations to the original AUP.

In instances of Non-Compliance or RAWI where an AUP is

- put 'On Hold,' the ACC Executive must disclose to the Animal-Based Scientist the associated immediate limitations to animal-based science activities; or
- 'Closed,' all animal-based science activities must cease until a new AUP is submitted to the ACC for review and approved by the ACC, as per *POL-002-A– Animal Use Protocols*.

For sanctions involving ‘On Hold’ or ‘Closure’, any live animals must be transferred to a Temporary Holding AUP, as per *POL-002–A–Animal Use Protocols*, and must remain under the direct oversight of the University Veterinarian until sanctions are formally lifted.

Appeals of ACC Decisions

Those wishing to appeal an ACC decision must submit their request in writing to the Director of Research Ethics and Compliance (Western Research).

- Adjudication will follow Western Research’s Appeals Policy.
- The RP may request mediation in advance of and/or during a formal appeal.

References

- Canadian Council on Animal Care
 - Policy on senior administrators responsible for animal care and use programs
 - Animal Care Committee Terms of Reference
 - CCAC Policy - Certification of Animal Ethics and Care Programs (2022)
 - Frequently Asked Questions – CCAC Reportable Animal Welfare Incidents
 -
- Government of Ontario
 - Animals for Research Act, R.S.O. 1990
- Western’s Senate
 - MAPP 1.43 – Safe Disclosure Policy
- Animal Care Committee policies and procedures

Revision History

Version	Date	Description of Changes	Author
00	7-10-2015	New Policy	LT/TDL
01	14-05-2020	Revised format; move core definitions to an Appendix; replace ‘PI’ with ‘Responsible Person’; add CCAC requirements for reporting major animal welfare incidents.	LT
02	11-03-2021	Update to include Major Animal Welfare Incidents throughout the policy; updated glossary	LT
03	19-01-2023	Update to RAWI (formerly MAWI) content and definition per CCAC’s updated FAQs document	LT

- *Acting in Good Faith* – A sincere belief or motive without any malice or the desire to defraud others. A sincere intention to deal honestly and fairly with others
- *Action Plans* – As it relates to the Concerns Policy (POL-004), specific actions associated with Non-Compliance that realign procedures with the approved Animal Use Protocol (AUP) and/or current regulatory / veterinary / institutional standards of animal ethics and care, and may include Sanctions, as directed by the Animal Care Committee Executive Working Group
- *Concerns* – As it relates to the Concerns Policy (POL-004), anything communicated to any member regarding animal health and/or welfare, human safety, and Animal Use Protocol (AUP)-related issues. Concerns that cannot be readily resolved will be reviewed by the Animal Care Committee (ACC) Executive, as appropriate
- *Incident* – As it relates to the Concerns Policy (see POL-004), a Concern that is substantiated by evidence provided to and reviewed by the Animal Care Committee (ACC) Executive, which requires project refinements. May be either administrative or procedural in nature
 - *Administrative Incident* – Substantiated concerns associated with *Animal Use Protocol* form content (e.g., animal use exceeds authorized numbers, overdue form renewals); outstanding Canadian Council on Animal Care (CCAC)-mandated training; or incomplete/inaccurate animal record-keeping
 - *Procedural Incident* – An incident that affects the health, behaviour and/or well-being of an animal that has either not been pre-approved on an Animal Use Protocol (AUP), or contravenes current regulatory, veterinary, or institutional standards of animal care and use; requires project refinement
- *Mortality* – Animals euthanized due to reaching humane intervention endpoint rather than experimental endpoint and those that are found dead.
- *Reportable Animal Welfare Incident (RAWI)* – As defined by the Canadian Council on Animal Care, an event that involves the observed mortality of $\geq 20\%$ above the AUP-approved baseline (per the Procedural Consequences) of the total number of animals by species per specific AUP Timeline onsite within a one-week timeframe. A reportable incident refers to:
 - a catastrophic failure of critical life support system(s);
 - disregard of, or unintended failure (human error) to follow, practices or procedures;
 - any other cause of significant mortality levels such as adverse outcomes or unforeseen circumstances; or
 - serious or continuous non-compliance with CCAC standards that leads to the suspension by the ACC or the Institution of an animal-based activity that threatens animal health or welfare.⁵

⁵ Canadian Council on Animal Care. Frequently Asked Questions - Certification of Animal Ethics and Care Programs (2019). Q. 1. pp.1. Retrieved from https://ccac.ca/Documents/Assessment/CCAC_frequently_asked_questions_CCAC_reportable_animal_welfare_incidents.pdf

Upon recommendation of the Institutional Veterinarian and as approved by the ACC Chair, exceptions may be granted for:

- Pilot Studies with unknown mortality rate, and
- other scenarios where the above parameters do not effectively represent the situation.
- **Non-Compliance** – A demonstrated disregard for animal-related regulatory, veterinary and/or institutional standards and related policies and procedures and/or a demonstrated lack of empathy for animals used in Animal-Based Science. Requires action plans and sanctions. May begin as an Incident or series of Incidents; if not readily resolved, may be considered to be Non-Compliance (see POL-004)
- **On Hold** – As determined by the Animal Care Committee (ACC) Executive on a case by case basis, actions taken to limit Animal-Based Science activities in the short-term until associated Concerns have been resolved (see POL-004). Limited activities may include one or more of the following:
 - Limiting Animal-Based Science activities, including but not limited to:
 - No new animal procurement
 - No experimental procedures
 - No breeding transfers out to research
 - No animals leave animal facility for experiments
 - Arms-length animal health professional/husbandry staff directly oversee animals
 - Fee for related services paid for by the Animal-Based Scientist
 - Limiting access to animals by Animal-Based Scientists and their staff, or a sub-set
 - Animals may be transferred to the Temporary Animal Holding Animal Use Protocol (AUP), as per POL-002 Animal Use Protocols
- **Project Refinements** – As it relates to the Concerns Policy (POL-004), adjustments to current AUP project parameters or related documentation pertaining to Incidents. Project refinements are initially proposed by the Animal Care Committee (ACC) Executive, communicated to the Animal-Based Scientist, and through discussion with the Animal-Based Scientist, agreed upon and implemented by the Animal-Based Scientist with support from the ACC or its designates, as required; may require submission of a Protocol Modification
- **Responsible Persons** – Individuals who, arising from their role within the institution and / or responsibilities as identified within an Animal Use Protocol (AUP), have direct accountability for the care and/or use of animals involved in Animal-Based Science. As per the attestation signed off within an AUP, AUP Holders are included as RPs in all situations where their direct reports are identified through the Concerns (POL-004) reporting process
- **Sanction** – As it relates to the Concerns Policy (POL-004), immediate measures taken in response to Non-Compliance or Major Animal Welfare Incident; may involve Animal Use Protocol (AUP) 'On Hold' or 'Closed' as directed by the Animal Care Committee (ACC) Executive
- **AUP Closure/Closed** – Full stoppage of an Animal Use Protocol by the ACC. The AUP is 'archived' in the system; final disposition of the animals will be determined the ACC Executive.