
Policy: Concerns Identification, Project Refinement and Corrective Response

Category: Post Approval Monitoring

Subject: Animal Care Committee assessment of and response to concerns involving a deviation from an approved Animal Use Protocol or current regulatory, veterinary and institutional standards of animal ethics and care.

Approving Authority: University Council on Animal Care

Responsible Office: Animal Care Committee (ACC)

Related Procedures: Procedures for Concerns Identification, Project Refinement and Corrective Response

Effective Date: 07OCT2015

Previous Approval Dates:

Revised:

Purpose

- To provide a framework for Western's Animal Care Committee (ACC) to effectively and collegially assess concerns and then respond to incidents and non-compliance pertaining to animal-based science.
- To 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.
- To ensure that appropriate project refinement in response to incidents, and action plans and/or sanctions in response to non-compliance, are promptly enacted by accountable parties.

Rationale

Western is obliged by its commitment to the Agreement on the Administration of Agency Grants and Awards by Research Institutions to fully comply with CCAC (Canadian Council on Animal Care) standards. Therefore, Animal Care Committees are required to establish and enact a post approval monitoring program that includes a framework 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.

Keys to the success of this program are effective collaborative communications between the Animal Care Committee, its representatives and the research community, and commitment by all parties to follow the policy and related procedures.

Scope

This policy applies to the animal-based science associated with Western's Research Community.

Definitions

- **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** – Specific actions associated with non-compliance that realign procedures with the approved AUP and/or current regulatory/veterinary/institutional standards of animal ethics and care, and may include sanctions, as directed by the Vice President-Research.
- **Agreement on the Administration of Agency Grants and Awards by Research Institutions** – Formerly, The Memorandum of Understanding – Tri-Agency's formal acknowledgment with Western committing this

institution to specific criteria that permits the release of funding. Compliance with this agreement is regularly audited by Tri-Agency in addition to CCAC's assessments

- **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.
- **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.
- **ACC Leaders** – The ACC Chair and Vice Chairs
- **Animal Care (AC) Facility Supervisor** – A trained, competent individual responsible for the oversight of an area or facility that houses research animals who is accountable to the ACVS Director as regards animal health and welfare related matters
- **ACVS Leaders** – ACVS Director, ACVS Assistant Director, Operations Manager and Veterinarian
- **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
- **Community Rep** – An ACC member that represents the public. A Community Rep must have no direct current or prior involvement in animal-based science
- **Concerns** – Anything communicated to any member regarding animal health and/or welfare, human safety, and AUP-related issues. Concerns that cannot be readily resolved 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
- **Concerns Identification & Follow-Up Procedures For Animal Care Facility Supervisors** - A flow chart and procedural outline that illustrate or describe the stepwise process for resolving concerns 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
- **Concerns Identification and Project Refinement Procedures – Step 1** - A flow chart and procedural outline that illustrate or describe the stepwise process for resolving Incidents
- **Concerns Identification And Corrective Response Procedures For Non-Compliance – Step 2** - A flow chart and procedural outline that illustrate or describe the stepwise process for resolving allegations of 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 an ACC Leader, ACVS Veterinarian, a Principal Investigator, or an AC Facility Supervisor
- **Animal Care (AC) Facility Supervisor** – A trained, competent individual responsible for the oversight of an area or facility that houses research animals who is accountable to the ACVS Director as regards animal health and welfare related matters
- **Incident** – A Concern that is substantiated by evidence provided to and reviewed by the ACC, 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 CCAC-mandated training; or incomplete/inaccurate animal record-keeping

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- **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 AUP, or contravenes current regulatory, veterinary or institutional standards of animal care and use. Requires project refinement
 - **Non-Compliance** – A demonstrated disregard for animal-related regulatory, veterinary and/or institutional standards and related policies and procedures; 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 by the ACC Executive Team as Non-Compliance
 - **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
 - **PI Representative (PI Rep)** – An animal user appointed by ACC Executive Team who agrees to act as a liaison between the PI associated with an Incident or Non-Compliance
 - **Project Refinements** – Adjustments to current AUP project parameters or related documentation pertaining to Incidents. Project refinements are initially proposed by the ACC Executive Team, communicated to the PI through a PI Rep, and through discussion with the PI, agreed upon and implemented by the PI with support from ACC designates, as required
 - **Protocol Modification** – A form used to submit requested post-AUP-approval changes/updates to the ACC.
 - **Sanction** – Immediate measures taken in response to non-compliance, e.g. AUP ‘on hold’, as directed by the Vice President-Research
 - **Senior Administration** – Vice President-Research, Faculty Chairs, Deans, and Scientific Directors
 - **Substantiated Concerns** – Concerns that are supported by evidence obtained by the ACC and considered to be Incidents requiring project refinements.
 - **UCAC** – University Council on Animal Care is Western’s senate committee ultimately responsible for the Animal Ethics and Care program at Western and its affiliates
 - **Vice President-Research (VP-R)** – The Senior Administrator of the animal care and use program associated with Western’s Research Community
 - **Western’s Research Community** – Institutions and their departments involving scientists having *Animal Use Protocols* under the jurisdiction of Western’s Animal Care Committee
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Policy

Where reasonable and appropriate, concerned individuals must attempt to work with Principal Investigators (PIs) to appropriately and promptly resolve concerns 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 (see Concerns Identification & Follow-Up Procedures for Animal Care Facility Supervisors).

All members of Western’s Research Community must promptly notify the ACC or its designates of any Concerns (see definition above) that have not been appropriately and promptly resolved through preliminary discussions between the concerned individual and Principal Investigators (PIs) and their staffs.

The UCAC and 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 in order to be classified further as Incidents (see definition above) requiring Project Refinements (see definition above) or Non-Compliance (see definition above) requiring Action Plans (see definition above) and/or Sanctions (see definition above).

All matters brought to the attention of ACC leadership must first be regarded as a Concern. If the Concern is substantiated, in general it must first be considered an Incident requiring adherence to the Concerns Identification and Project Refinement Procedures – Step 1 (see definition above). If the Incident is not resolved

through Step 1, or if the ACC Executive believes that a situation may be considered Non-Compliance, the Concerns Identification and Corrective Response Procedures for Non-Compliance – Step 2 process must be followed (see definition above).

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

ACVS Veterinarians must ensure that animals involved in procedural Incidents and Non-Compliance promptly receive medical interventions to relieve unnecessary suffering.

The ACC must promptly inform the Principal Investigator (PI) of Concerns brought to its attention, and must regularly communicate with the PI throughout assessment and response processes.

Principal Investigators and their staffs must be afforded opportunities to provide the ACC Executive Team (see definition above) with clarifications and to express any discomfort regarding proposed Project Refinements (see definition above) relating to Incidents or Action Plans relating to allegations of Non-Compliance.

The ACC, Principal Investigators, Animal Care Facility Supervisors, and their designates must act collegially in good faith to readily resolve any Incidents associated with animals under their care.

For instances involving allegations of Non-Compliance,

- the Vice President-Research must support the ACC by providing direction regarding Action Plans and Sanctions
- applicable Senior Administration must be advised of non-compliance allegations and proposed Action Plans, as directed by the VP-Research and implemented by the ACC or its Executive Team.

Incidents and Non-Compliance, related Project Refinements, Action Plans, Sanctions, and follow-up must be documented by the ACC and made readily available to Senior Administrators and regulators.

Non-Compliance Action Plans must be communicated to granting agencies via Research Western's Grants Office.

The Animal Use Protocol must be updated via a Protocol Modification form to reflect alterations to or clarifications arising from Incidents and/or Non-Compliance.

Roles and Responsibilities

Animal well being is the joint responsibility of the PIs and their staffs, Animal Care staffs and their supervisors, and ACVS Veterinarians. A solid foundation of good communication between the PI lab and Animal Facility staff acting in good faith is the basis of professional research, which should resolve most concerns without the necessity of involving the ACC or its Executive Team.

- Vice-President Research (VPR) is responsible to:
 - provide direct support to the ACC, as requested
 - provide timely direction to the ACC Executive Team regarding action plans and sanctions in response to non-compliance
- UCAC is responsible to:
 - provide direct support to the ACC, as requested
 - appoint a pool of PI Reps that adequately represents the spectrum of research within Western's research community
 - consider appeals from the PI

- ACC is responsible to:
 - appoint an ACC Executive Team
 - appoint designates to act on their behalf
 - recommend a pool of ACC PI Reps to the UCAC
 - review and provide timely feedback to the Executive Team regarding their proposed action plans and the VPR's sanction recommendations for non-compliance
- ACC Executive Team is responsible to:
 - objectively assess evidence associated with Concerns presented to the ACC
 - ensure prompt response to incidents and non-compliance
 - assign an appropriate PI Representative from the UCAC pool of PI Reps to each incident that is not readily resolved
 - develop initial recommendations for Action Plans
 - seek VPR direction on actions in response to Non-Compliance, e.g. Action Plans & Sanctions
 - follow-up with the PI to ensure Action Plans have been implemented
- ACC Chair is responsible to:
 - maintain an objective position
 - communicate regularly with the ACC and Faculty appointed PI Reps, VP-Research, ACVS Leaders and the PI, as appropriate
 - ensure timely and appropriate communications between the PI and the ACC
- ACC Coordinator is responsible to:
 - send communications to ACC members regarding upcoming ACC Executive Team meetings
 - record and promptly distribute meeting minutes associated with Concerns, Incidents and Non-Compliance
- ACVS Leaders are responsible to:
 - provide administrative and technical support to the ACC regarding continuing care assurance through
 - Incident and Non-Compliance case administration and record-keeping
 - consultation with the ACC and its designates regarding veterinary and regulatory standards of care
 - provide technical and consultative support to the PI towards aligning animal-research practices with the approved AUP and/or all regulatory standards through
 - dialogue
 - animal model & drug regime refinement
 - hands-on demonstrations
 - staff training
 - AUP documentation refinement
 - act as a designate of the ACC as regards supporting the PI in implementing Project Refinements, Action Plans and Sanctions, as directed by the ACC
- ACVS Veterinarians are responsible to:
 - advise the ACC of current veterinary standards
 - perform or authorize a competent designate to treat or euthanize an animal as directed by Action Plans or Sanctions

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- work with the PI to implement Project Refinements and/or Action Plans
 - Compliance Officers are responsible to:
 - follow-up directly with the PI / PI group to facilitate prompt resolution of any Concerns
 - forward any Concerns that cannot be readily resolved between the Compliance Officer and the PI / PI group to the ACC Executive Team
 - act as designates of the ACC in undertaking regular rounds of areas associated with their roles, implementing Project Refinements, Action Plans and Sanctions, as directed by the ACC
 - submit compliance rounds reports to the ACC for review at full meetings at a frequency determined by the ACC
 - Animal Care (AC) Facility Supervisors and/or their designates are responsible to:
 - provide day-to-day assistance and information with respect to animal care and use to animal scientists and animal care staff in remaining compliant with approved AUPs and institutional and CCAC standards by ensuring
 - Animal scientists and their staffs are comfortable handling animals and carrying out procedures successfully, and that they are able to do so in appropriate conditions
 - Endpoints are applied as approved by the ACC to avoid unnecessary distress to animals
 - where reasonable and appropriate, communicate directly with PIs and their staffs concerns 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
 - inform the ACC Executive or its designates of any animal health and welfare concerns that are not readily resolved through direct work with the PI and PI staff
 - act as a designate of the ACC as regards implementing Project Refinements, Action Plans and Sanctions, as directed by the ACC
 - Senior Administrators are responsible to:
 - support the ACC Executive Team and VP-R in implementing Action Plans and Sanctions associated with Non-Compliance
 - participate in identified Non-Compliance response discussions
 - Principal Investigator is responsible to:
 - work promptly with AC Facility Supervisors to address any of their concerns 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
 - be available to ACC representatives throughout the process
 - collegially interact with ACC representatives
 - provide clarifications to ACC representatives, as requested
 - promptly implement ACC Project Refinements and/or Action Plans
 - PI Representative is responsible to:
 - be available to the ACC when called upon to act as a liaison between the PI and the ACC
 - objectively and collegially communicate with the PI on behalf of the ACC
 - objectively represent the PI's feedback to the ACC, VP-R and other Senior Administrators

Related Documents / References

- MAPP 1.43 - Safe Disclosure Policy
- MAPP 7.15 - Post Approval Monitoring Program
- MAPP 7.12 – Policy for the Use of Animals in Research, Testing and Teaching
- MAPP 7.10 – Standardized Training in Animal Care and Use
- Animal Care & Use Records Policy
- Animal Procurement Policy
- Animal Use Protocols Policy
- Animals for Research Act
- Sick Animal Response Policy
- CALAM Standards of Veterinary Care