Steps associated with responding to a ‘Concern’ - anything communicated to any member regarding animal health and/or welfare, human safety, and AUP-related issues associated with animal-based science activities within Western and affiliates – are outlined within a series of flow charts appended to this document, as follows:

- **PROC-004-A** – Procedures for Responding to Concerns – Laboratory Animal Facility Supervisors outlines the steps Facility Supervisors will follow when a ‘concern’ is brought to their attention.

- **PROC-004-B** – Procedures for Responding to Concerns outlines the steps ACC Executive members will follow when a ‘Concern’ is brought to its attention. This flow chart outlines the response steps for substantiated Concerns considered to be ‘Incidents.’

- **PROC-004-C** – Procedures for Responding to Concerns – Non-Compliance outlines the steps ACC Executive members will follow when a ‘Non-Compliance’ is identified.

- **PROC-004-D** – Procedures for Responding to Concerns – Concerned Individual outlines the roadmap for any individual having a ‘concern,’ as defined above.

- **PROC-004-E** – Procedures for Responding to Concerns – Concern Report Template contains the report template for use by Facility Supervisors, Institutional Veterinarians and the ACC Executive as they respond to Concerns. Completed forms must be maintained in a readily retrievable format for regulatory review.

- **PROC-004-F** – Procedures for Responding to Major Animal Welfare Incidents (MAWIs) outlines the steps ACC Executive members will follow when a ‘MAWI’ is identified.

- **PROC-004-G** – Major Animal Welfare Incident Self-Reporting Form contains CCAC’s required form.

### Revision History

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Description of Changes</th>
<th>Author</th>
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<tr>
<td>00</td>
<td>07-10-15</td>
<td>New procedure</td>
<td>ACC Executive</td>
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<tr>
<td>01</td>
<td>12-07-18</td>
<td>Two procedures added:PROC-004-D (concerned individual) &amp; E (log and report templates previously approved); Main Procedures document created; significant refinements to PROC-004 A, B and C</td>
<td>ACC Executive</td>
</tr>
<tr>
<td>02</td>
<td>14-05-20</td>
<td>Updates to the format.</td>
<td>ACC Executive</td>
</tr>
<tr>
<td>03</td>
<td>11-03-21</td>
<td>Add PROC-004-F &amp; G re. MAWIs</td>
<td>LT</td>
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</table>
Facility Supervisors - A Concern identified by Animal Care staff or other source is forwarded to the Facility Supervisor

Step A.1 – Fact-Finding - Facility Supervisor collects and reviews information associated with the concern by fact-finding and communicating directly with AC and PI staff

- OH&S Related=YES
  - Step A.2A - Facility Supervisor immediately forwards OH&S concern to Animal Research Safety Consultant / Institutional OHS

- Animal Health Related=NO
  - Step A.2B - Facility Supervisor works directly with the PI &/or Vet (animal health concern only) &/or Animal Research Safety Consultant (OH&S only) to resolve the concern

- Animal Health Related=YES
  - Step A.2C - Facility Supervisor proceeds as per the POL-004-Sick Animal Response Policy & Procedures (PROC-004)

As necessary ACVS Veterinarian intervenes to provide relief to animals experiencing unnecessary pain or suffering & contributes animal health professional expertise to the Executive / ACC

Step A.3 – Facility Supervisor updates involved AC & PI staff & Vet on actions taken and resolution status

- Readily Resolved
  - Step A.4 – Facility Supervisor maintains records for internal purposes only

- Not Readily Resolved
  - Step A.3A – Facility Supervisor forwards Concern Report to ACC Executive & updates involved AC staff on actions taken and resolution status

As necessary OH&S officer/consultant to intervene for non-compliance involving potential threats to health & safety of personnel

A.4A - For corresponding process, follow PROC-004-B & PROC-004-C
For ACC Executive – A Concern (Concern Report) identified by someone that has not been readily resolved between the concerned individual and the Responsible Person (RP), as appropriate, is forwarded to the ACC Executive

1.1 – ACC Office saves original report; opens new file/updates Concern Report (CR); forwards w. associated info to ACC Executive and/or ACC Leader

1.2 - ACC Leader or Designate reviews Concern to determine its status by fact-finding & communicating directly with the Responsible Person (RP)

1.3 - ACC Executive determines Concern type - Incident or Non-Compliance

1.4 – ACC Executive determines proposed refinements commensurate with the degree of impact upon the animal & with reference to related roles; ACC Leader or Designate may act as primary liaison; communicates directly with the RP; attempts to come to consensus regarding needed refinements; all communications are logged & relayed to ensure up-to-date information is shared with appropriate stakeholders - This step may be initiated @ 1.2

Consensus

1.5 – RP implements agreed upon project refinements; submits associated Protocol Modification form, as appropriate; updates the ACC Executive liaison

1.6 – ACC Executive follows-up with PI to confirm project refinements have been implemented

No Consensus

Resolved

1.7 – ACC Executive emails PI acknowledging Incident resolution & associated agreements; other impacted stakeholders are notified, as appropriate

Not Resolved

1.8 – ACC Office updates & closes Concern Report; all associated communications are filed.

1.3A- ACC Executive or Designate updates RP & source of Concern

1.3B – ACC Office updates, closes & files Concern Report

1.4A - Go to PROC-004-C Procedures for Non-Compliance

As necessary Veterinarian intervenes to provide relief to animals experiencing unnecessary pain or suffering & contributes animal health professional expertise to the Executive / ACC

As necessary OH&S officer/consultant to intervene for Incidents involving potential threats to health & safety of personnel

Incident – A Concern that is substantiated by evidence provided to and reviewed by the 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 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 AUP, or contravenes current regulatory, veterinary or institutional standards of animal care and use. Requires project refinement

APP B - Procedures for Responding to Concerns - Incidents

ACC Executive

Western Research

Approval Date: 14MAY2020
Effective Date: 14MAY2020

PROC-004-01-B
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 Non-Compliance.
An individual identifies a ‘concern’ with respect to any aspect of the animal ethics and care program within Western’s Research Community.

Notification - The individual brings the concern to the attention of the responsible person, OR his/her direct supervisor, OR contacts either ACC leaders (acc@uwo.ca) or the Vice President - Research (vpr@uwo.ca) relaying information pertaining to the nature of the concern.

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, as appropriate.

Animal Care Committee (ACC) – The institutional animal care committee under the Vice President-Research “responsible for overseeing all aspects of animal care and use and for working with animal users, animal care personnel and the institutional administration” (CCAC); 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.
## CONCERN DATA

<table>
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<tr>
<th>CONCERN ID</th>
<th>CONCERN TYPE</th>
<th>DATE REPORTED DD/MMM/YYYY</th>
<th>DATE CLOSED DD/MMM/YYYY</th>
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## PRINCIPAL INVESTIGATOR (AUP) / ACC RESPONDER CONTACT INFORMATION / OTHER INVOLVED PERSONS

<table>
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<tr>
<th>ROLE</th>
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## CONCERN LOCATION INFORMATION

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## CONCERN NARRATIVE

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<tr>
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<th>TIME</th>
<th>Chronological Details Of Events &amp; Follow-Up Actions</th>
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## SUPPORTING DOCUMENTATION

<table>
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<th>DOCUMENT DETAILS – Source, Recipient, Subject/Title</th>
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<td>Concern ID:</td>
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<td>Approved:</td>
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15-May-20

|   |   |
For ACC Executive – MAWI Response
ACC Executive Team has identified a ‘Major Animal Welfare Incident’

2.1 – As appropriate to the situation, ACC Leader / VPR or Designate imposes immediate sanctions while disseminating and/or collecting information to/from involved parties
- ACC Leader notifies the Responsible Person(s) (RPs) of immediate actions taken in response to the situation

2.2 – ACC Leader meets with the RP(s) to review the situation and receive feedback
Throughout the process all communications / information are/is logged and relayed to appropriate stakeholders, including the RP (Principal Investigator)

2.3 – ACC Leader, VPR or Designate notifies the CCAC within 10 days of confirmation.
- Develops initial recommendations w. associated timeframes
- Once action plan is finalized, ACC Leader notifies in writing the RP(s), full ACC, VPR, Grants Office, Facility Supervisor, as appropriate

2.4 – ACC Leader and/or Designate liaises with the RP(s) regarding action plan implementation and requests / relays updates throughout the process, as appropriate

2.5 – ACC Leader and/or Designate follows-up with RP(s) and then updates the ACC Executive and other applicable stakeholders regarding action plan implementation status

2.6 – ACC Executive notifies applicable stakeholders of changes towards resolution

2.7 – ACC Leader emails the RP(s) acknowledging MAWI resolution & indicating nature of any further expectations
ACC Leader notifies other stakeholders, e.g. VPR, Sr. Administration, Facility Supervisor, CCAC

2.8 – MAWI Report & associated Concern Report are updated, closed, distributed (MAWI to CCAC) & electronically filed by ACC Office

Major Animal Welfare Incident (MAWI) – An event that leads to the unanticipated death of research, teaching and testing animals, or poses an immediate and significant threat to animal health or welfare. A major incident can refer to: a catastrophic failure of critical life support system(s) that leads to the death of research teaching or testing animals, or poses a significant threat to animal health or welfare; disregard of, or unintended failure to follow, practices or procedures that leads to the death of research, teaching or testing animals, or poses a significant threat to animal health or welfare; significant and unanticipated morbidity or mortality unrelated to the above; or serious or continuous noncompliance with CCAC standards that leads to the suspension by the animal care committee or the institution of an animal-based activity that threatens animal health or welfare

As necessary ACVS Veterinarian intervenes to provide relief to animals experiencing unnecessary pain or suffering & contributes animal health professional expertise to the Executive / ACC

As necessary OH&S officer/consultant to intervene for non-compliance involving potential threats to health & safety of personnel

Mediation / Appeal options are available via Western Research

PROC-004-02-F
Approved: 11MAR2021
Effective: 11MAR2021
The Canadian Council on Animal Care (CCAC) requires certified institutions to self-report major animal welfare incidents within 10 days of their occurrence as outlined in the CCAC policy: Certification of animal ethics and care programs (CCAC, 2019).

A major animal welfare incident refers to an event that leads to the unanticipated death of research, teaching or testing animals, or poses an immediate and significant threat to animal health or welfare.

If you are unsure of whether an event should be reported, please contact the CCAC.

Examples of major incidents include:

- a catastrophic failure of critical life-support system(s);
- disregard of, or unintended failure to follow approved practices or procedures;
- significant and unanticipated morbidity or mortality unrelated to the above; and
- serious or repeated noncompliance with CCAC standards that leads to the suspension by the animal care committee or the institution of an animal-based activity that threatens animal health or welfare.

This form should be completed and signed by the animal care committee chair and sent to the CCAC. A copy should also be forwarded to the senior administrator responsible for the animal ethics and care program at the institution.

Please forward this form to the Director of Assessment and Certification:

Dr. Michael Baar
Canadian Council on Animal Care
190 O’Connor Street, Suite 800
Ottawa, ON, K2P 2R3
613-238-4031 ext. 226
mbaar@ccac.ca
MAJOR ANIMAL WELFARE INCIDENT SELF-REPORTING FORM

**Contact Information**

<table>
<thead>
<tr>
<th>Name of institution</th>
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<tr>
<th>Name of senior administrator responsible for the animal ethics and care program</th>
<th>Email</th>
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<tr>
<th>Date(s) of event</th>
<th>Protocol numbers (if applicable)</th>
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**Incident Description**

Describe chronologically what happened in detail. Include information about: nature/cause of the event, number and/or percentage of animals and species affected, location, outcomes of the incident, impacts on animals.
Procedures for Responding to Concerns
Major Animal Welfare Incident Self-Reporting Form

PROC-004-G

### Notification

Please indicate the key individual(s) within your animal ethics and care program who were notified, and when.

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
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### Resolution and Mitigation

Describe the steps that were taken following the incident, and what actions are being implemented to prevent similar occurrences.

☐ I certify that the information provided above is correct to the best of my knowledge.

Animal care committee chair name: .................................................................

Signature: .................................................................

Date of report: .................................................................