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’s Research Community – 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.

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**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>
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<tr>
<td>02</td>
<td>14-05-20</td>
<td>Updates to the format.</td>
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PROC-004-02
Approved: 14MAY2020
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

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

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

Step A.3A – Facility Supervisor forwards Concern Report to ACC Executive & updates involved AC staff on actions taken and resolution status

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

No 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

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

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

Substantiated=YES

Substantiated=NO

Non-Compliance

Incident

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

PROC-004-01-B
Approval Date: 14MAY2020
Effective Date: 14MAY2020
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
**Animal Care Committee**

**APP D - Procedures for Responding to Concerns**

**Concerned Individual**

**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

- **Supervisor**
  - Unresolved
  - Contact ACC
    - acc@uwo.ca or VPR
    - vpr@uwo.ca

- **AC Facility Supervisor**
  - Go to PROC-004-A

- **ACC/VPR**
  - ACC/VPR leader reaches out directly to the concerned individual to obtain further detail. If VPR office is initially involved, ACC leader is notified of concern.
  - Go to PROC-004-B and/or PROC-004-C

**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
**Animal Care Committee**

**Concern Report**

**Date:** ENTER DATE

**Concern ID:** C-XXX (OFFICE USE)

15-May-20

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**CONCERN DATA**

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**PRINCIPAL INVESTIGATOR (AUP) / ACC RESPONDER CONTACT INFORMATION / OTHER INVOLVED PERSONS**

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**CONCERN LOCATION INFORMATION**

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**CONCERN NARRATIVE**

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**SUPPORTING DOCUMENTATION**

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**PROC-004-E**

Approved: 14MAY2020