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 Reportable Animal Welfare Incidents (RAWIs) outlines the steps ACC Executive members will follow when a ‘RAWI’ is identified.

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

### Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Description of Changes</th>
<th>Author</th>
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<tbody>
<tr>
<td>00</td>
<td>07-10-2015                               New procedure                               ACC Executive</td>
<td></td>
</tr>
<tr>
<td>01</td>
<td>12-07-2018                               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>14-05-2020                               Updates to the format.                       ACC Executive</td>
<td></td>
</tr>
<tr>
<td>03</td>
<td>11-03-2021                               Add PROC-004-F &amp; G re. RAWIs                  LT</td>
<td></td>
</tr>
<tr>
<td>04</td>
<td>19-01-2023                               Updated PROC-004-F &amp; -G to RAWIs per CCAC   LT</td>
<td></td>
</tr>
</tbody>
</table>
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=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

- **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)

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

- **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 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

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

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)

Substantiated=YES

Substantiated=NO

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

Incident

Non-Compliance

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

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

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

1.4A - 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

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

Resolved

Not Resolved

1.6A – ACC Executive returns to 1.3

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.

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-004-04-B
Approval Date: 19JAN2023
Effective Date: 19JAN2023
### For ACC Executive – Non-Compliance Response

ACC Executive Team has identified a Concern as ‘Non-Compliance’

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
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<tbody>
<tr>
<td>2.1</td>
<td>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 sanction(s) and allegations and requests.</td>
</tr>
<tr>
<td>2.2</td>
<td>ACC Leader meets with the RP(s) to review allegations and receive feedback. Throughout the process, all communications/information are/is logged and relayed to appropriate stakeholders, including the RP (Principal Investigator).</td>
</tr>
<tr>
<td>2.3</td>
<td>ACC Leader develops initial recommendations w. associated timeframes; electronically forwards to Executive requesting immediate feedback. Executive provides feedback to ACC Leader. Once action plan is finalized, ACC Executive notifies in writing the RP(s), full ACC, VPR, Grants Office, Facility Supervisor, as appropriate.</td>
</tr>
<tr>
<td>2.4</td>
<td>ACC Leader and/or Designate liaises with the RP(s) regarding action plan implementation and requests / relays updates throughout the process, as appropriate.</td>
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<td>2.5</td>
<td>ACC Leaders and/or Designate follows-up with RP(s) and then updates the ACC Executive and other applicable stakeholders regarding action plan implementation status.</td>
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<tr>
<td>2.6</td>
<td>ACC Executive notifies applicable stakeholders of changes to previously imposed sanctions.</td>
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<tr>
<td>2.7</td>
<td>ACC Executive emails the RP(s) acknowledging non-compliance resolution &amp; indicating nature of any further expectations. ACC Executive notifies other impacted stakeholders, e.g. Sr. Administration, Facility Supervisor.</td>
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<tr>
<td>2.8</td>
<td>Non-Compliance Report is completed &amp; electronically filed by ACC Office.</td>
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<tr>
<td>2.9</td>
<td>As applicable, within 10 days of classification, the ACC Executive submits to CCAC the Major Animal Welfare Incident Self-Reporting Form.</td>
</tr>
</tbody>
</table>

**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.

<table>
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<tr>
<th>Not Resolved</th>
<th>Resolved</th>
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<tr>
<td>2.6.A – ACC Chair convenes a meeting with VPR, University Vet &amp; other Sr. Admin to determine follow-up actions, e.g. further sanctions, subsequent meeting with RP(s).</td>
<td>ACC Executive notifies applicable stakeholders of changes to previously imposed sanctions.</td>
</tr>
</tbody>
</table>

**Non-Compliance** – As necessary, ACVS Veterinarian intervenes to provide relief to animals experiencing unnecessary pain or suffering & contributes animal health professional expertise to the Executive / ACC |

**Non-Compliance** – 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**
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.
CONCERN DATA – ACC USE ONLY

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

<table>
<thead>
<tr>
<th>ROLE</th>
<th>NAME</th>
<th>LOCATION</th>
<th>CONTACT INFORMATION</th>
<th>AUP INFORMATION</th>
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CONCERN LOCATION INFORMATION

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<th>LOCATION</th>
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<th>ROOM PURPOSE</th>
<th>AREA SUPERVISOR</th>
<th>SUPERVISOR CONTACT INFO</th>
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CONCERN NARRATIVE

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<th>DATE ##/mmm/YYYY</th>
<th>Chronological Details of Events &amp; Follow-Up Actions</th>
<th>STEP #</th>
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Page 1 of 3
PROC-004-04-E
Approved: 19JAN2023
Effective: 19JAN2023
## SUPPORTING DOCUMENTATION – Please append all associated documentation along with this report

<table>
<thead>
<tr>
<th>#</th>
<th>TYPE</th>
<th>DATE</th>
<th>DOCUMENT DETAILS – Source, Recipient, Subject/Title</th>
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Submit the completed form and associated support documentation to acc@uwo.ca
For ACC Executive – RAWI Response

ACC Executive Team has identified a ‘Reportable Animal Welfare Incident’

2.1 – As appropriate to the situation, ACC Leader or Compliance Vet 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 or Compliance Vet notifies the CCAC within 14 days of the RAWI using the CCAC Reportable Animal Welfare Incident Initial Notification Form
   - Develops initial recommendations w. associated timeframes
   - Once action plan is finalized, ACC Leader notifies in writing the RP(s), Executive, VPR, Grants Office, Facility Supervisor, as appropriate

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

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

2.6 – ACC Leader notifies applicable stakeholders of actions taken towards resolution, including CCAC using the CCAC Reportable Animal Welfare Incident Form

2.7 – ACC Leader emails the RP(s) acknowledging RAWI resolution & indicating nature of any further expectations
   ACC Leader notifies other stakeholders

2.8 –RAWI Report & associated Concern Report are updated, closed, distributed & electronically filed by ACC Office

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Reportable Animal Welfare Incident (RAWI) – an event that involves the observed mortality of ≥20% above the AUP-approved baseline 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. 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.
**RAWI Initial Notification Form Instructions**

Certified institutions must notify the Canadian Council on Animal Care (CCAC) of reportable animal welfare incidents within 14 days of occurrence, whether resolved or not, as outlined in the CCAC policy: Certification of ethical animal care and use programs.

A CCAC reportable animal welfare incident refers to an event that leads to significant mortality for animals used in research, teaching, or testing, or poses an immediate and significant threat to animal health or welfare. If you are unsure of whether an event should be reported, please promptly contact the CCAC.

Please provide as much preliminary information as possible. At this point, the CCAC is primarily interested in knowing if animals are still at risk, and if immediate safeguards have been put in place to avoid reoccurrence. Details about the incident, the review conducted by the animal care committee and their decisions, or the correction of deficiencies (e.g., equipment replacement, refinement/development of procedures) should be part of follow-up reporting using the CCAC Reportable Animal Welfare Incident Form. If all of the information about an incident can be provided within 14 days of occurrence, institutions can use the CCAC Reportable Animal Welfare Incident Form instead.

This form should be completed and signed by the animal care committee chair, the attending veterinarian, or a delegate and sent to the CCAC. A copy should also be forwarded to the senior administrator responsible for the ethical animal care and use program at the institution.

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Approved: 19JAN2023
Effective: 19JAN2023
CCAC REPORTABLE ANIMAL WELFARE INCIDENT INITIAL NOTIFICATION FORM

Contact Information
Name of institution
Name of senior administrator responsible for the ethical animal care and use program
Name of animal care committee chair
Name of attending veterinarian
Protocol numbers (if applicable)

Date(s) of event
Email
Email

Incident Description
Nature and cause (if known) of the event:

Option A
Complete this section if the approved protocol includes more than one objective/component and the objectives/components are independent. Provide information for each objective/component affected by the incident.

Number of mortalities: per species, per objective/component, per day since the start of the event:

Number of approved animals per species, per objective/component, on site at the time of the incident:

Approved % mortality baseline for the relevant objective/component.

Option B
Complete this section if the approved protocol includes only one overall objective/component. Provide information for each protocol affected by the incident.

Number of mortalities per species, per day since the start of the event:

Number of approved animals per species, on site at the time of the incident:

Approved % mortality baseline for the protocol:

Number of animals (and their species) still at risk:

Immediate safeguards put in place to prevent reoccurrence:

1 See the CCAC frequently asked questions: CCAC reportable animal welfare incidents, Question 7.
2 Ibid, Question 10.
3 See the CCAC frequently asked questions: CCAC reportable animal welfare incidents, Question 1.
4 Ibid, Question 7.
5 Ibid, Question 10.
6 Ibid, Question 1.
☐ I certify that the information provided above is correct to the best of my knowledge.
Animal care committee chair, attending veterinarian, or delegate:

Signature:
Date of report:
RAWI ANIMAL WELFARE INCIDENT FORM INSTRUCTIONS

The Canadian Council on Animal Care (CCAC) requires certified institutions to send notification of reportable animal welfare incidents within 14 days (2 weeks) of their occurrence, as outlined in the CCAC policy: Certification of ethical animal care and use programs.

A CCAC reportable animal welfare incident refers to an event that leads to significant mortality for animals used in research, teaching, or testing, or poses an immediate and significant threat to animal health or welfare. If you are unsure of whether an event should be reported, please promptly contact the CCAC.

Examples of CCAC reportable incidents include:

- catastrophic failure of critical life support systems or its components (e.g., malfunction of power supply, HVAC, pumps, filters, watering system, alarms, sensors, call-out systems, etc.);
- disregard of, or unintended failure (human error) to follow practices or procedures (e.g., not following approved SOPs or other procedures, miscommunication, etc.);
- any other cause of significant mortality such as adverse outcomes or unforeseen circumstances;

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.

Provide as much detail as possible about the incident, the review conducted by the animal care committee and their decisions, and the correction of deficiencies (e.g., equipment replacement, refinement/development of procedures). If you only have preliminary information at this point, please use the CCAC Reportable Animal Welfare Incident Initial Notification Form.

This form should be completed and signed by the animal care committee chair, the attending veterinarian, or a delegate and sent to the CCAC. A copy should also be forwarded to the senior administrator responsible for the ethical animal care and use program at the institution.²

---

1 See the CCAC frequently asked questions: CCAC reportable animal welfare incidents, Question 7.
2 Ibid, Question 10.
3 See the CCAC frequently asked questions: CCAC reportable animal welfare incidents, Question 1.
4 Ibid, Question 7.
5 Ibid, Question 10.
6 Ibid, Question 1.
Procedures for Responding to Concerns
App G2 – CCAC’s Reportable Animal Welfare Incident Form

Contact Information
Name of institution
Name of senior administrator responsible for the ethical animal care and use program
Name of animal care committee chair
Name of attending veterinarian
Protocol numbers (if applicable)

Date(s) of event
Email
Email

Incident Description
Nature and cause (if known) of the event:

Option A
Complete this section if the approved protocol includes more than one objective/component and the objectives/components are independent. Provide information for each objective/component affected by the incident.

Number of mortalities\(^1\) per species, per objective/component, per day since the start of the event:

Number of approved animals per species, per objective/component, on site at the time of the incident\(^2\):

Approved % mortality baseline\(^3\) for the relevant objective/component:

Option B
Complete this section if the approved protocol includes only one overall objective/component. Provide information for each protocol affected by the incident.

Number of mortalities\(^4\) per species, per day since the start of the event:

Number of approved animals per species, on site at the time of the incident\(^5\):

Approved % mortality baseline\(^6\) for the protocol:

Describe the incident chronologically and in detail. Include information about the nature and cause of the event, the location, outcomes of the incident, and impacts on animals

Notification
Please indicate the key individuals within your ethical animal care and use program who were notified, and when.

Name: Role: Date:
Name: Role: Date:

\(^1\) See the CCAC frequently asked questions: CCAC reportable animal welfare incidents, Question 7.
\(^2\) Ibid, Question 10.
\(^3\) Ibid, Question 1.
\(^4\) Ibid, Question 7.
\(^5\) See the CCAC frequently asked questions: CCAC reportable animal welfare incidents, Question 10.
\(^6\) Ibid, Question 1.
Resolution and Mitigation Steps Taken to Date
Describe the steps that were taken following the incident, and what actions are being implemented to prevent similar occurrences, if known at the time of completing this report.

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

Animal care committee chair, attending veterinarian, or delegate:

Signature:
Date of report: