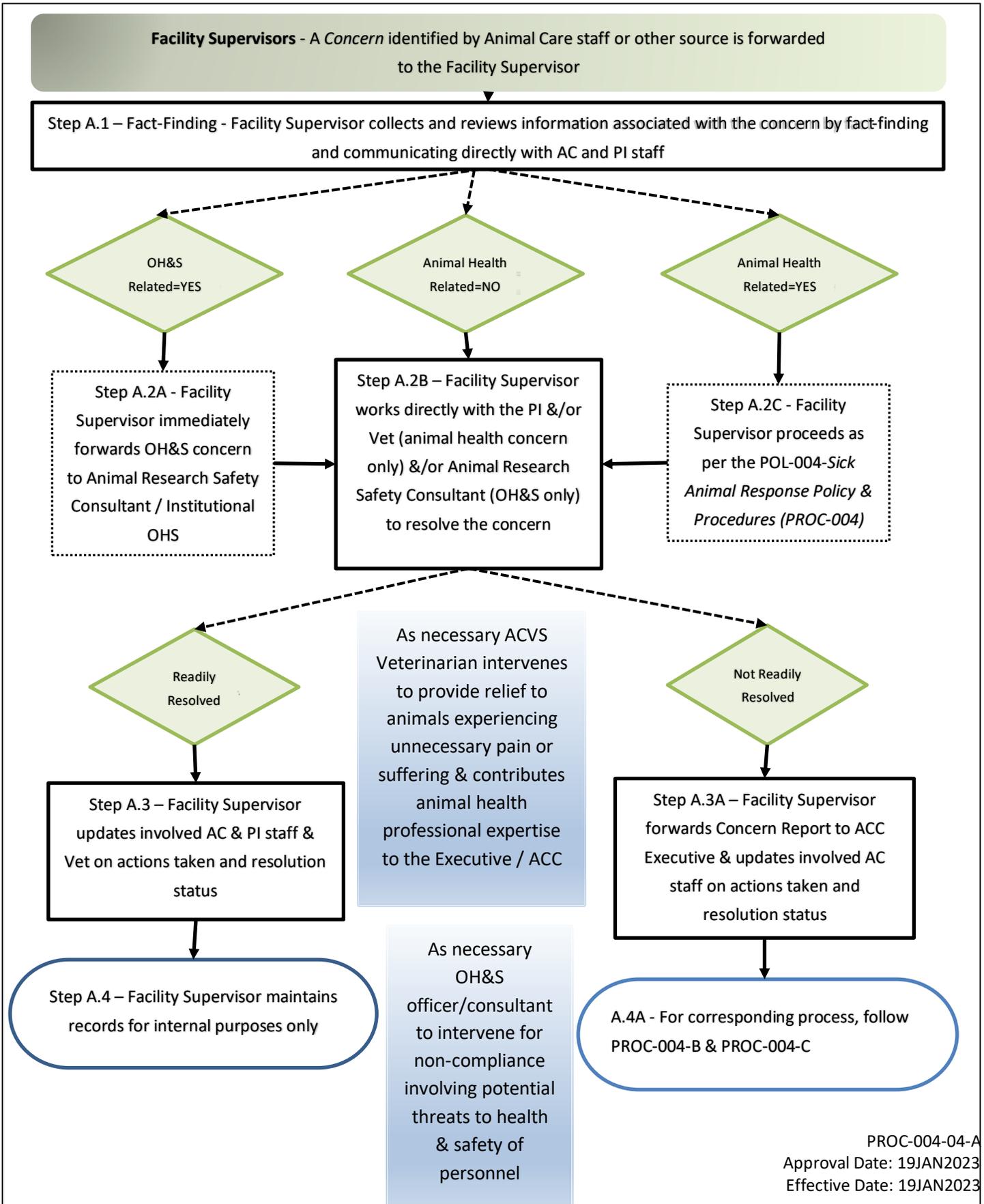


Steps associated with responding to a ‘Concern’ - anything communicated to any member regarding animal health and/or welfare, human safety, and AUP-related issues associated with animal-based science activities within Western and affiliates – are outlined within a series of flow charts appended to this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

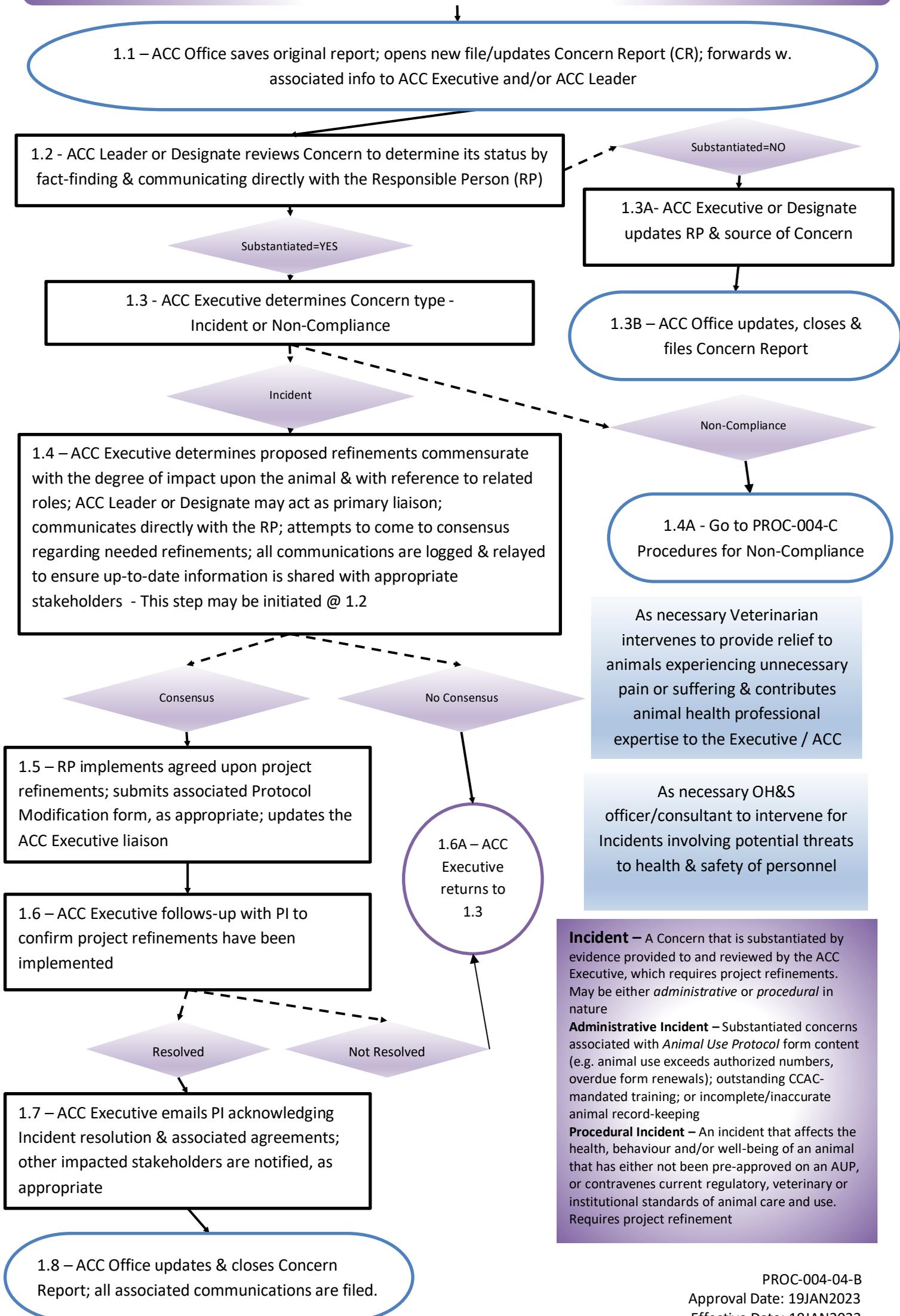
- **PROC-004-A – Procedures for Responding to Concerns – Laboratory Animal Facility Supervisors** outlines the steps Facility Supervisors will follow when a ‘concern’ is brought to their attention.
- **PROC-004-B – Procedures for Responding to Concerns** outlines the steps ACC Executive members will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

	Date	Description of Changes	Author
00	07-10-2015	New procedure	ACC Executive
01	12-07-2018	Two procedures added: PROC-004-D (concerned individual) & E (log and report templates previously approved); Main Procedures document created; significant refinements to PROC-004 A, B and C	ACC Executive
02	14-05-2020	Updates to the format.	ACC Executive
03	11-03-2021	Add PROC-004-F & G re. MAWIs	LT
04	19-01-2023	Updated PROC-004-F & -G to RAWIs per CCAC	LT



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



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

For ACC Executive – Non-Compliance Response

ACC Executive Team has identified a Concern as 'Non-Compliance'

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 sanction(s) and allegations and requests

2.2 – 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)

2.3 – 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

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

Resolved

2.6 – ACC Executive notifies applicable stakeholders of changes to previously imposed sanctions

2.7 – ACC Executive emails the RP(s) acknowledging non-compliance resolution & indicating nature of any further expectations – ACC Executive notifies other impacted stakeholders, e.g. Sr. Administration, Facility Supervisor

2.8 – Non-Compliance Report is completed & electronically filed by ACC Office

2.9 – As applicable, within 10 days of classification, the ACC Executive submits to CCAC the Major Animal Welfare Incident Self-Reporting Form

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

Not Resolved

2.6.A – ACC Chair convenes a meeting with VPR, University Vet & other Sr. Admin to determine follow-up actions, e.g. further sanctions, subsequent meeting with RP(s)

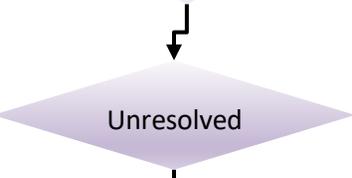
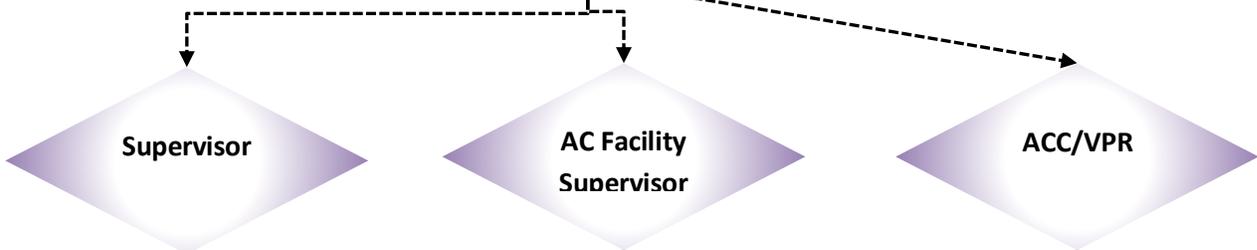
As necessary ACVS Veterinarian intervenes to provide relief to animals experiencing unnecessary pain or suffering & contributes animal health professional expertise to the Executive / ACC

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

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



Contact ACC acc@uwo.ca or VPR vpr@uwo.ca

Go to PROC-004-A

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				
CONCERN ID	CONCERN TYPE U=Unclassified I=Incident NC=Non-Compliance	DATE REPORTED DD/MMM/YYYY	DATE CLOSED DD/MMM/YYYY	CONCERN SUMMARY
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap to enter a date.	Click or tap to enter a date.	Click or tap here to enter text.

PRINCIPAL INVESTIGATOR (AUP) / ACC RESPONDER CONTACT INFORMATION / OTHER INVOLVED PERSONS				
ROLE	NAME	LOCATION	CONTACT INFORMATION	AUP INFORMATION
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

CONCERN LOCATION INFORMATION				
LOCATION	ROOM #S	ROOM PURPOSE	AREA SUPERVISOR	SUPERVISOR CONTACT INFO
Click or tap here to enter text.				

CONCERN NARRATIVE		
DATE ##/mmm/YYYY	Chronological Details of Events & Follow-Up Actions	STEP #
Click or tap to enter a date.	Click or tap here to enter text.	
Click or tap to enter a date.	Click or tap here to enter text.	
Click or tap to enter a date.	Click or tap here to enter text.	
Click or tap to enter a date.	Click or tap here to enter text.	
Click or tap to enter a date.	Click or tap here to enter text.	
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Click or tap to enter a date.	Click or tap here to enter text.	

SUPPORTING DOCUMENTATION – <i>Please append all associated documentation along with this report</i>			
#	TYPE	DATE	DOCUMENT DETAILS – Source, Recipient, Subject/Title
1	Choose an item.	Click or tap to enter a date.	Click or tap here to enter text.
2	Choose an item.	Click or tap to enter a date.	Click or tap here to enter text.
3	Choose an item.	Click or tap to enter a date.	Click or tap here to enter text.
4	Choose an item.	Click or tap to enter a date.	Click or tap here to enter text.
5	Choose an item.	Click or tap to enter a date.	Click or tap here to enter text.
6	Choose an item.	Click or tap to enter a date.	Click or tap here to enter text.
7	Choose an item.	Click or tap to enter a date.	Click or tap here to enter text.
8	Choose an item.	Click or tap to enter a date.	Click or tap here to enter text.
9	Choose an item.	Click or tap to enter a date.	Click or tap here to enter text.
10	Choose an item.	Click or tap to enter a date.	Click or tap here to enter text.

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

Resolved

Not Resolved

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

2.6.A – ACC Chair convenes a meeting with VPR, Compliance Vet & other Sr. Admin to determine follow-up actions, e.g., further sanctions, subsequent meeting with RP(s)
- ACC Chair updates CCAC via rawi@ccac.ca

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

Reportable Animal Welfare Incident (RAWI) – an event that involves the observed mortality of $\geq 20\%$ 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 ¹

¹ CCAC. CCAC Reportable Animal Welfare Incident Initial Notification Form (Feb 2022). Retrieved 19JAN2023 from:
https://ccac.ca/Documents/Assessment/CCAC_Reportable_Animal_Welfare_Incident_Initial_Reporting_Form.pdf

**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	Date(s) of event
Name of animal care committee chair	Email
Name of attending veterinarian	Email
Protocol numbers (if applicable)	

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 mortalities¹ 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 incident²:

Approved % mortality baseline³ 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 mortalities⁴ per species, per day since the start of the event:

Number of approved animals per species, on site at the time of the incident⁵:

Approved % mortality baseline⁶ 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.

**Procedures for Responding to Concerns
App G1 – CCAC’s Reportable Animal Welfare Incident
Initial Notification Form**

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

² CCAC. CCAC Reportable Animal Welfare Incident Form (2022). Retrieved 19JAN2023 from: https://ccac.ca/Documents/Assessment/CCAC_Reportable_Animal_Welfare_Incident_Form.pdf

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.

Contact Information

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

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 mortalities¹ 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 incident²:

Approved % mortality baseline³ 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 mortalities⁴ per species, per day since the start of the event:

Number of approved animals per species, on site at the time of the incident⁵:

Approved % mortality baseline⁶ 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.

**Procedures for Responding to Concerns
App G1 – CCAC’s Reportable Animal Welfare Incident
Initial Notification Form**

Name:

Role:

Date:

Name:

Role:

Date:

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: