

Procedures for Responding to Concerns

PROC-004

Approval Date: 12JUL2018 Effective Date: 12JUL2018

### **Procedures for Responding to Concerns**

**Procedure Number: PROC-004** 

**Version Number: 01** 

Category: Post Approval Monitoring

Subject: Steps for responding to any concerns regarding the animal ethics and care program

**Approving Authority:** Animal Care Committee **Responsible Office:** Animal Care Committee

Related Policy: Concerns Identification, Project Refinement and Corrective Response (POL-004)

Approval Date: July 12, 2018 Effective Date: July 12, 2018

Previous Approval Dates: October 7, 2015

Revised:

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 - Facility Supervisors
 outlines the steps Animal Care Facility Supervisors will follow when a 'concern' is brought
 to their attention.

- PROC-004-B Procedures for Responding to Concerns Step 1 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 Step 2 Non-Compliance outlines the steps ACC Executive members will follow when a noncompliance 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 Log and Concern Report Templates contains the log and report templates for use by AC Facility Supervisors and the ACC Executive as they respond to concerns. Completed forms must be maintained in a readily retrievable format for regulator review.



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## **Revision History**

Version	Date	Description of Changes	Author
00	07-10-15	New procedure	ACC Executive
01	12-07-18	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



**Procedures for Responding to Concerns** 

## Facility Supervisors

PROC-004-A

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Effective Date: 12JUL2018 Facility Supervisors - A Concern identified by Animal Care staff or other source is forwarded to the Animal Care (AC) Facility Supervisor Step A.1 - Fact-Finding - AC Facility Supervisor collects and reviews information associated with the concern by factfinding and communicating directly with AC and PI staff Step A.2 – AC Facility Supervisor starts an AC internal record (Concern Report) OH&S Animal Health Animal Health Related=YES Related=YES Related=NO Step A.3 - AC Facility **AC Facility Supervisor** Step A.3.A- AC Facility Supervisor works directly with immediately forwards Supervisor proceeds as the PI &/or Vet (animal health OH&S concern to Animal per the Sick Animal concern only) &/or Animal Research Safety Response Policy & Research Safety Consultant Consultant **Procedures** (OH&S only) to resolve the concern As necessary Not Readily Readily Institutional Resolved Resolved Veterinarian intervenes to provide relief to Step A.4 - AC Facility Supervisor animals updates involved AC & PI staff & experiencing unnecessary pain or Vet on actions taken and suffering resolution status Step A.5 - AC Facility Supervisor Step A.5A - AC Facility Supervisor updates & files AC internal record forwards Concern Report to ACC (Concern Report) & adds note to Executive & updates involved AC facility monthly Facility Supervisor's staff on actions taken and **Continuing Care Report** resolution status

For corresponding process, see PROC-004-B & PROC-004-C - Steps 1 & 2

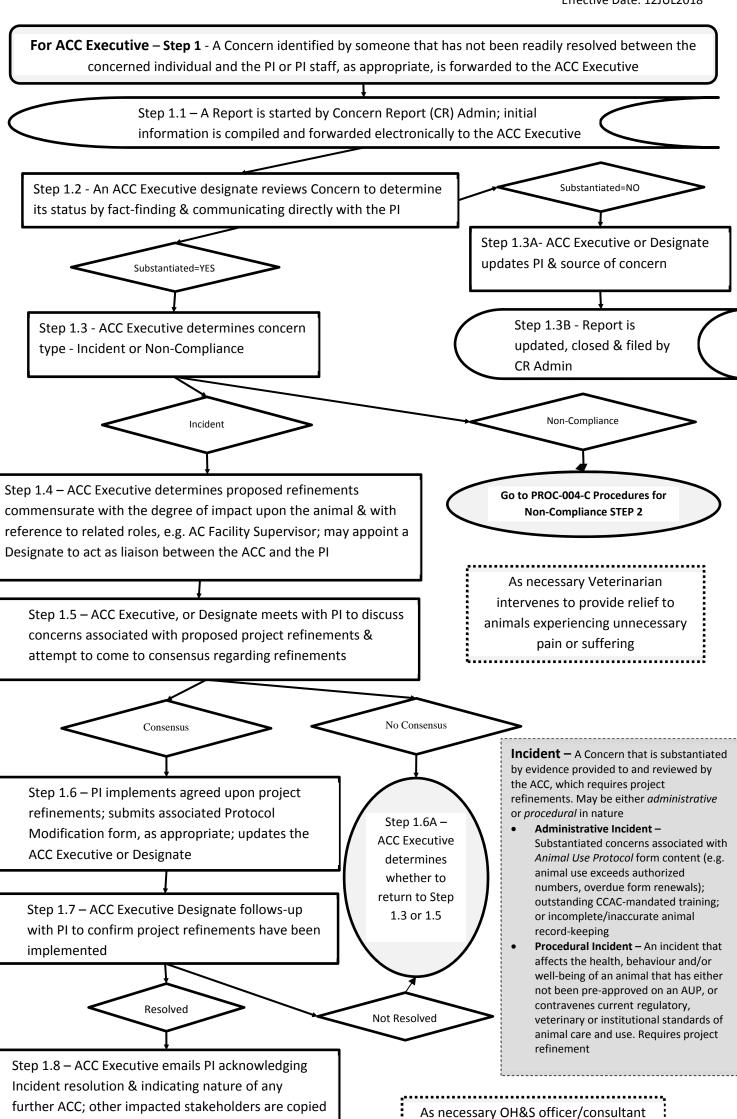


Procedures for Responding to Concerns -Step 1

**ACC Executive** PROC-004-B

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to intervene for Incidents involving potential threats to health & safety of personnel

on the email, e.g. AC Facility Supervisor

Step 1.9 –Report is completed by CR admin & electronically filed



Procedures for Responding to Concerns-Step 2

Non-Compliance Response ACC Executive

PROC-004-C

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For ACC Executive – Step 2 – Non-Compliance Response - ACC Executive Team has identified a Concern as 'Non-Compliance'

Step 2.1 – As appropriate to the situation, ACC Executive / VPR or Designate imposes immediate sanctions while collecting additional information and/or disseminating information to involved parties.

Step 2.2 – ACC Executive develops initial recommendations w. associated timeframes; electronically forwards to full ACC and VP (Research) requesting immediate feedback; ACC provides feedback to ACC Executive

Step 2.3 – Once action plan is finalized and confirmed via Step C, ACC liaises with PI regarding its implementation

Step 2.4 – As required, action plan is implemented by ACC & its designates; ACC Executive updates VPR, other Senior Administration, as applicable, Grants Office & AC Facility Supervisor

Step 2.5 – PI implements action plan & updates the ACC Executive on actions taken

Step 2.6 – ACC designate follows-up with PI, and then updates the ACC Executive to confirm PI implementation of action plan



Step 2.7 – ACC Executive directs stakeholders to lift any sanctions

Step 2.8 – ACC Executive emails PI acknowledging non-compliance resolution & indicating nature of any further ACC follow-up & related timelines; other impacted stakeholders are copied on the email, e.g. ACC, VPR, other Sr. Administration, AC Facility Supervisor

Step 2.9 – Non-Compliance Report is

Step 2.7.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 PI

As necessary ACVS

Veterinarian intervenes to provide relief to animals experiencing unnecessary pain or suffering

completed, electronically filed by CR admin

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

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 as Non-Compliance

PI may submit formal appeal to UCAC



**Procedures for Responding to Concerns** 

## **Concerned Individual**

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An individual identifies a 'concern' with respect to any aspect of the animal ethics and care program Notification - The individual brings the concern to the attention of the responsible person, OR his/her direct supervisor, OR contacts either ACC leaders (auschair@uwo.ca) or the Vice President (Research) (vpr@uwo.ca) relaying information pertaining to the nature of the concern ACC/VPR **AC Facility Supervisor** Supervisor Go to PROC-004-A ACC /VPR leader reaches out Unresolved directly to the concerned individual to obtain further detail. If VPR office is initially involved, ACC leader is notified of concern. Contact ACC / VPR leader Go to PROC-004-B and/or PROC-004-C Concerns – Anything communicated to any member Steps 1 & 2 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) – 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" (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 – <a href="mailto:auscraft">auschair@uwo.ca</a> / <a href="mailto:vpr@uwo.ca">vpr@uwo.ca</a>



**Procedures for Responding to Concerns** 

# Concern Report Log

### PROC-004-E Approval Date: 12JUL2018 Effective Date: 12JUL2018

PRINCIPAL INVESTIGATOR (PI) CONTACT INFORMATION						
PI NAME PI PHONE# PI EMAIL PI OFFICE/LAB LOCATION						
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ANIMAL USE PROTOCOL INFORMATION								
AUP#	AUP SPECIES	Cl <sup>1</sup>	OTHER DETAIL					
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Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐ AUP Summary is attached					

	CONCERN LOG							
CONCERN TYPE *2 & ID #3	DATE REPORTED ddmmmyyyy	DATE RESOLVED ddmmmyyyy	CONCERN SUMMARY <sup>4</sup>					
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<sup>&</sup>lt;sup>1</sup> CI – Category of Invasiveness

 $<sup>^{2}</sup>$  C=CONCERN, I= INCIDENT, N=NON-COMPLIANCE

 $<sup>^3</sup>$  CONCERN ID# - 001, 002 etc. used to track related information throughout Concern Report

<sup>&</sup>lt;sup>4</sup> CONCERN TITLE – Summary of concern type, e.g. lack of post-operative analgesics, incomplete monitoring records, agents used not on AUP



**Procedures for Responding to Concerns** 

# **Concern Report Log**

PROC-004-E

Approval Date: 12JUL2018 Effective Date: 12JUL2018

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### **Animal Care Committee**

**Procedures for Responding to Concerns** 

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Concern Report

PROC-004-E Approval Date: 12JUL2018

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Effective Date: 12JUL2018

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PRINCIPAL INVESTIGATOR (PI) & PI DESIGNATE(S) CONTACT INFORMATION									
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PI DESIGNATE NAME PI [			PI DI	ESIGNATE	#	PI DESIGNATE EMA	IL	PI DESIGNATI LOCA	·
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	CONCERN DATA								
CONCERN TYPE *5 & ID # <sup>6</sup>	DATE REPORTED ddmmmyyyy	RES	DATE SOLVED CONCERN SUMMARY <sup>7</sup> nmmyyyy						
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ANIMAL FACILITY INFORMATION									
FACILITY S		S	SUPERVIS	OR	SUP	ERVISOR PHONE # & EMAIL		IMAL HOUSING & OCEDURE ROOM #s	CONTAINMENT LEVEL

	CONCERN NARRATIVE					
DATE	CONCERN DETAILS					
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<sup>&</sup>lt;sup>5</sup> C=CONCERN, I= INCIDENT, N=NON-COMPLIANCE

 $<sup>^{6}</sup>$  CONCERN ID# - 001, 002 etc. used to track related information throughout Concern Report

<sup>&</sup>lt;sup>7</sup> CONCERN TITLE – Summary of concern type, e.g. lack of post-operative analgesics, incomplete monitoring records, agents used not on AUP



**Procedures for Responding to Concerns** 

Concern Report PROC-004-E

Approval Date: 12JUL2018 Effective Date: 12JUL2018

		Effective Date: 123012016					
	ACTIONS TAKEN						
DATE	INVOLVED PERSONS	ACTIONS TAKEN					
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SUPPORTING DOCUMENTATION							
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text.							
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text.							

 $<sup>^{8}\,</sup>INFORMATION\,SOURCE\,-\,Email,\,animal\,monitoring/scoring\,record,\,voice mail,\,in-person\,conversation$