

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:

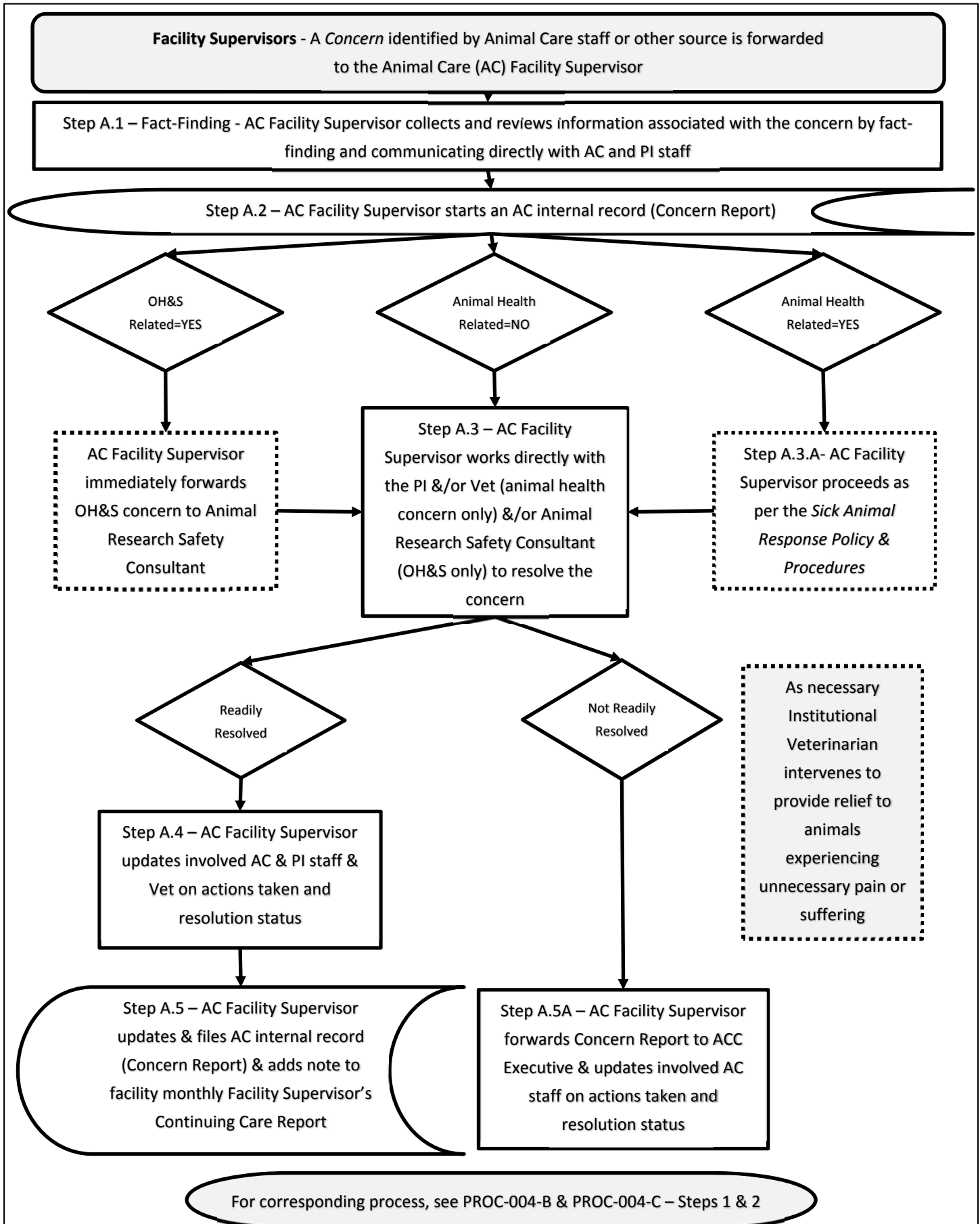
Steps associated with responding to a 'concern' - anything communicated to any member regarding animal health and/or welfare, human safety, and AUP-related issues associated with animal-based science activities within Western's Research Community – are outlined within a series of flow charts appended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

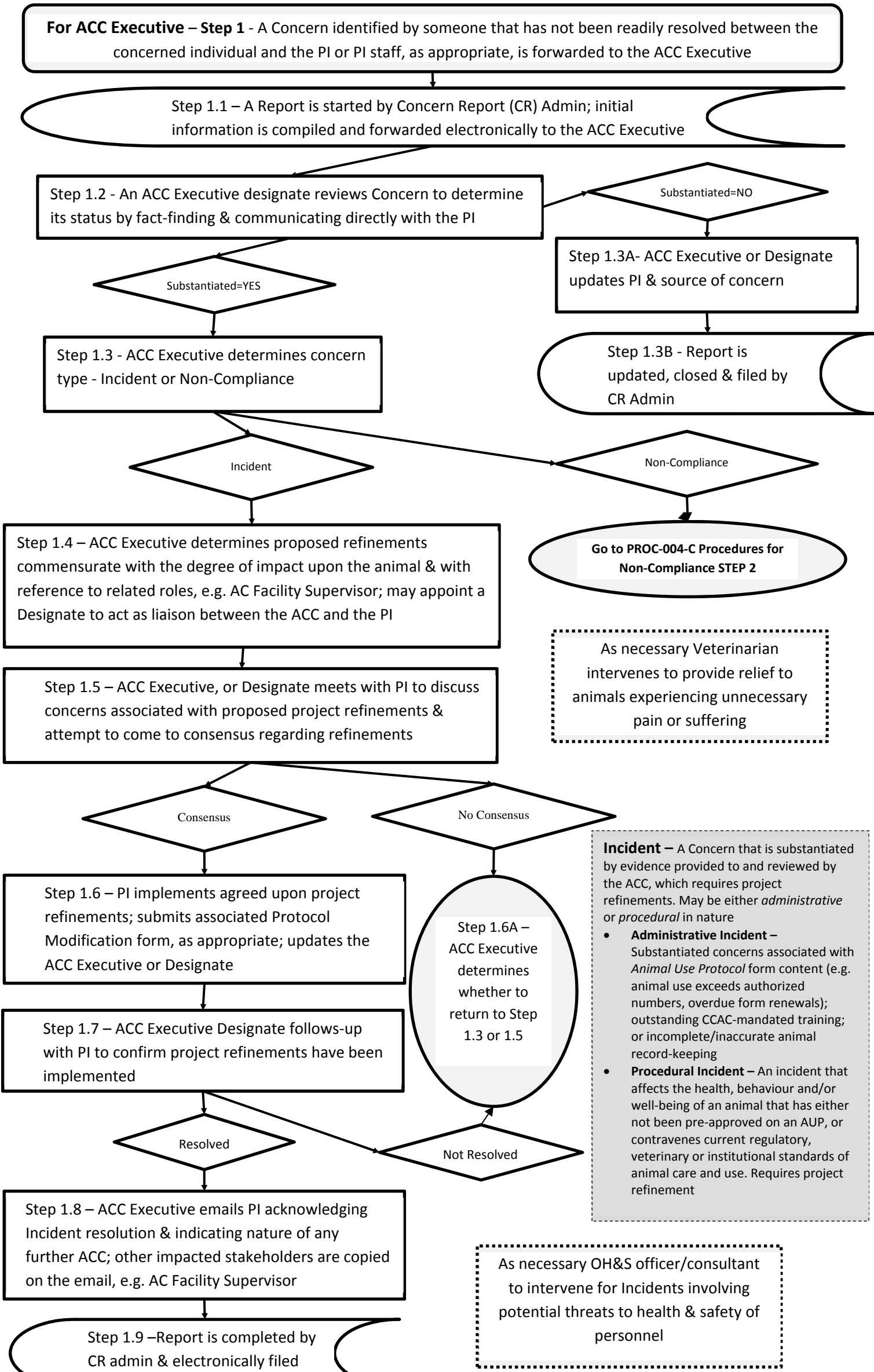
- **PROC-004-A – Procedures for Responding to Concerns – Facility Supervisors** outlines the steps Animal Care Facility Supervisors will follow when a 'concern' is brought to their attention.
- **PROC-004-B – Procedures for Responding to Concerns – Step 1** – outlines the steps ACC Executive members 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 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 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.



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





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 2.7.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

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

As necessary ACVS Veterinarian intervenes to provide relief to animals experiencing unnecessary pain or suffering

Step 2.9 – Non-Compliance Report is completed, electronically filed by CR admin

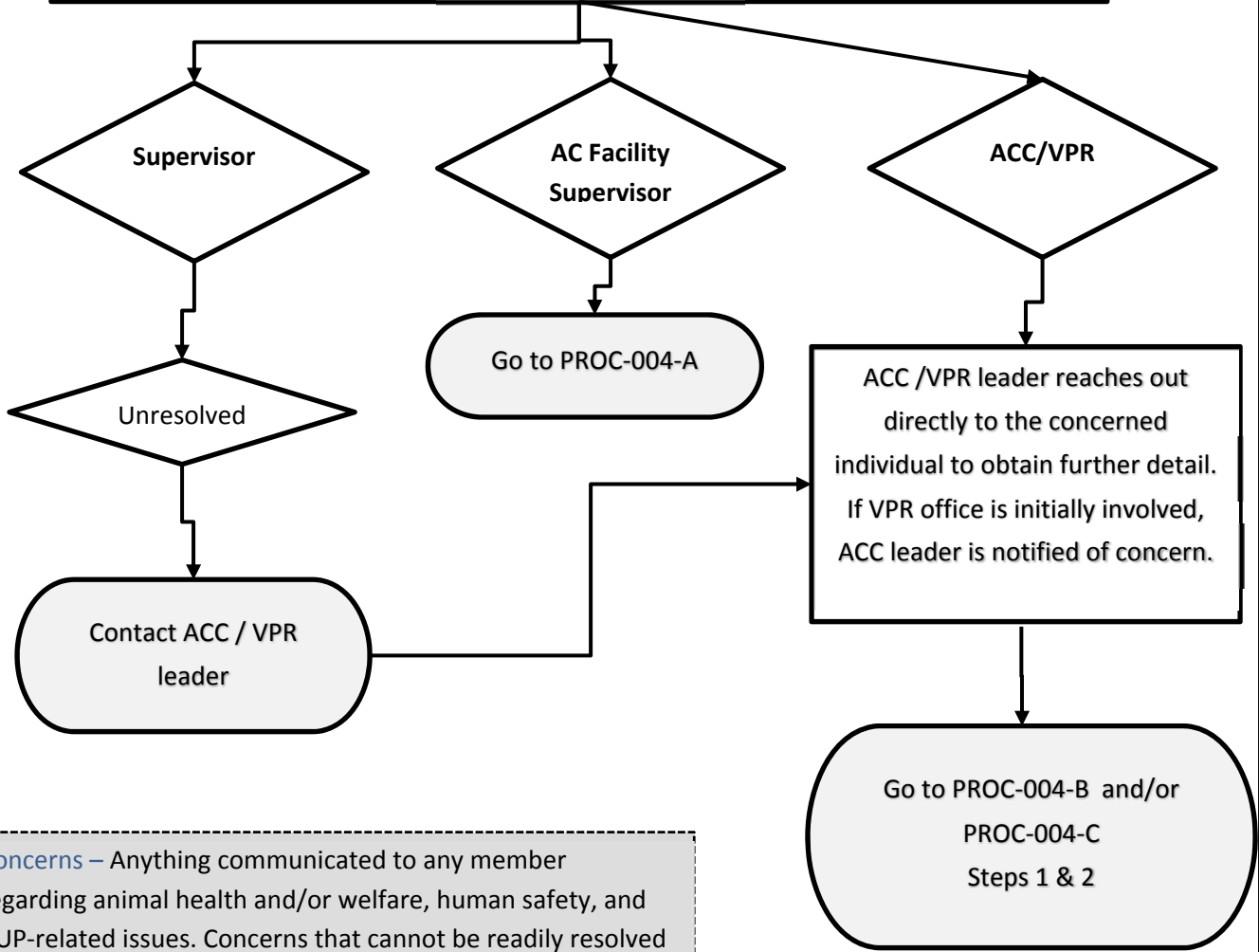
As necessary OH&S officer/consultant to intervene for non-compliance involving potential threats to health & safety of personnel

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

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



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) – 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 – auschair@uwo.ca / vpr@uwo.ca



PRINCIPAL INVESTIGATOR (PI) CONTACT INFORMATION			
PI NAME	PI PHONE#	PI EMAIL	PI OFFICE/LAB LOCATION
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.

ANIMAL USE PROTOCOL INFORMATION			
AUP #	AUP SPECIES	CI ¹	OTHER DETAIL
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	<input type="checkbox"/> AUP Summary is attached
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	<input type="checkbox"/> AUP Summary is attached

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

² C=CONCERN, I= INCIDENT, N=NON-COMPLIANCE

³ CONCERN ID# - 001, 002 etc. used to track related information throughout Concern Report

⁴ CONCERN TITLE – Summary of concern type, e.g. lack of post-operative analgesics, incomplete monitoring records, agents used not on AUP



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OTHER DETAIL	
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PRINCIPAL INVESTIGATOR (PI) & PI DESIGNATE(S) CONTACT INFORMATION					
PI NAME		PI PHONE#	PI EMAIL	PI OFFICE/LAB LOCATION	
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PI DESIGNATE NAME		PI DESIGNATE #	PI DESIGNATE EMAIL	PI DESIGNATE OFFICE/LAB LOCATION	
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 DATA					
CONCERN TYPE * ⁵ & ID # ⁶	DATE REPORTED <i>ddmmmyyyy</i>	DATE RESOLVED <i>ddmmmyyyy</i>	CONCERN SUMMARY ⁷		
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.		
ANIMAL FACILITY INFORMATION					
FACILITY	SUPERVISOR	SUPERVISOR PHONE # & EMAIL	ANIMAL HOUSING & PROCEDURE ROOM #s	CONTAINMENT LEVEL	
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CONCERN NARRATIVE	
DATE	CONCERN DETAILS
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⁵ C=CONCERN, I= INCIDENT, N=NON-COMPLIANCE

⁶ CONCERN ID# - 001, 002 etc. used to track related information throughout Concern Report

⁷ CONCERN TITLE – Summary of concern type, e.g. lack of post-operative analgesics, incomplete monitoring records, agents used not on AUP

ACTIONS TAKEN		
DATE	INVOLVED PERSONS	ACTIONS TAKEN
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SUPPORTING DOCUMENTATION	
INFORMATION SOURCE ⁸	DOCUMENT OUTLINE
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⁸ INFORMATION SOURCE – Email, animal monitoring/scoring record, voicemail, in-person conversation
Concerns that cannot be readily and appropriately resolved through preliminary discussions between the concerned individual and PIs and their staffs must be forwarded to the ACC Executive via ausexec@uwo.ca