The University of Western Ontario

POST APPROVAL
MONITORING PROGRAM
PRESENTATION OUTLINE

- Western’s Context
- PAM Goal & Mandate
- PAM Development
- PAM Core Elements
  - Roles & Responsibilities
  - Non-Compliance Response Defined
  - Non-Compliance Response Processes
Western’s Post Approval Monitoring Program

Western’s Context
Western’s & LHSC’s Animal Use Statistics

- ~200 citywide researchers using:
- 72,289 animals (2009) within:
  - 12 regulated & 3 AUS approved non-regulated animal facilities, and
  - 20 field research projects
Species

- 3,415 Fish
- 52,893 Mice
- 176 Pigs
- 202 Hamsters
- 22 Dogs
- 165 Frogs
- 3,773 Birds
- 8,937 Rats
- 1,875 Bats
- 15 Sheep
- 115 Guinea Pigs
- 58 Cats
- 181 Rabbits
- 4 Rhesus
- 14 Cynos
Western’s Animal Care Committee Structure

- University Council on Animal Care (UCAC)
- Animal Care Governance Steering Committee (ACGSC)
- Animal Use Subcommittee (AUS)
- Animal Care & Veterinary Services
AUS Functional Components

**Full AUS**
- Monthly Meetings - Full Review Workflow
  - AUS Protocol Review SOP Sect.C.2.3
- PAM - Non-compliance response, Regular Reports/Updates
- Policy & Process Approval

**Protocol Review Committee Meetings**
- Weekly Meetings – Designated Review Workflow
  - AUS Protocol Review SOP Sect.C.2.2
- PAM updates as necessary

**Facility Manager/Compliance Officer/ACVS Meetings**
- Monthly updates, policy & procedure development, PAM updates involving citywide facility managers, compliance officer, AUS AO’s, ACVS Vets & Operations Manager

**Non-Compliance Response Teams**
- Teams consisting of Protocol Support Vet and AUS PI Representatives under the direct guidance of AUS committee Chair, and ACVS Director

**Policy & Process Development Subcommittee**
- Ad hoc meetings of PI’s, facility managers, & ACVS staff facilitated by ACVS Director/Operations Manager
ACVS Functional Components That Support The AUS

**CENTRAL ADMINISTRATION**
- ACVS Director, Operations Manager, Financial Officer
  - SOP Records Management
  - AUS Policy and Procedure Development Assistance
  - AUS New Member Orientation Development & Presentation

**AUS ADMIN OFFICERS**
- 2 AUS Admin. Officers
  - Regulatory Reports – Annual Animal Use Data Form, OMAFRA
  - AUS Meetings Facilitation - Minutes, Reports, Scheduling, Reminders & Approval Notices Documentation & Distribution
  - AUS New Member Orientation Development & Presentation Support
  - Animal Use Number Collection & Reporting
  - Animal Care & Use Training for all Researchers & Staff/Students
    - Core Course, Web CT, Hands-on Workshops
  - Post Approval Monitoring including AUS Site Visits, Veterinary Site Visits, Non-Compliance Response
    - see AUS Post Approval Monitoring Program

**RESEARCH COMPLIANCE & EDUCATION**
- PS Vet, Teaching Vet, Teaching Coordinator, Teaching Assistant
ACVS Functional Components That Support the AUS

HSAC, WV, RRI
ANIMAL FACILITIES
2 Facility Managers,
2 Lead Hands,
13 Animal Caretakers,
3 Maintenance Staff

RESEARCH
SUPPORT
Clinical Vet, 3 RVTs

Post Approval Monitoring
see AUS Post Approval Monitoring Program

Monthly Facility Update Reports

Facility-related AUP Review

Animal Health Monitoring

Veterinary Site Visit Support

SOP Development

Research Veterinary Support

Research Animal Model Development
Western’s Post Approval Monitoring Program

PAM Goal & Mandate
PAM Program Goals

- Collaborative & collegial approach
- Alignment with *Animal Use Protocol* elements
- Conformity with regulatory & institutional requirements
PAM Mandate

ACC to establish a PAM program that:

- Defines roles and responsibilities
- Develops effective non-compliance response procedures
Western’s Post Approval Monitoring Program

PAM Development
## PAM Program Development

### Benchmark
- CCAC’s Terms of Reference for ACC’s (2006)
- Other Institutions

### Form Multi-Stakeholder Subcommittees
- Multiple face-to-face PAM program development meetings
- Email review subcommittee

### Develop the PAM Framework
- Define Roles & Responsibilities
- Define Non-Compliance
- Outline Non-Compliance Response Processes

### Create PAM Policy Documentation
- Ownership by Western’s senior animal care committee

### Implement PAM Program
- Administered by AUS with ACVS support
Western’s Post Approval Monitoring Program

PAM Core Elements
PAM Core Elements

Roles & Responsibilities
Roles & Responsibilities – Identified Major PAM Sources

1. Animal Health Program
2. AUS Site Visits
3. Veterinary Rounds
4. Compliance Officer Site Visits
5. Animal Facility Staff
6. Ad Hoc Veterinary Visits
7. AUS Admin. Office
8. ACVS Animal Training Program
9. Regulatory Site Visits
Roles & Responsibilities – Defined PAM-Specific Roles

- ACVS Veterinarians
- AUS Chair/Vice-Chair
- AUS PI Rep
- Institutional Compliance Officers
- Animal Facility Managers
- ACVS Director
- AUS Admin. Officers
- ACVS Animal Training Coordinators
- Protocol Support Veterinarian
Roles & Responsibilities – Protocol Support Veterinarian (PS Vet)

- Manage PAM Processes
- Facilitate Site Visits: AUS, Veterinary, Ad Hoc, Regulatory Body
- Liaise with & Support PAM Roles
- Lead Non-Compliance Response
- Record & Report PAM Activities to AUS
Roles & Responsibilities – AUS PI Rep

Peer Liaison Between Animal Users & AUS

Active AUS Meeting Participation

Assist AUS Chair & PS Vet in Non-Compliance Resolution
PAM Core Elements

Non-Compliance Response Defined
Non-Compliance Types

**Procedural**
- Administrative – No Animal Impact
- Outstanding Training - No Animal Impact
- Incomplete Animal Record Keeping
- Limited Animal Impact

**Ethical**
- Animal procedure causing pain or distress not pre-approved in the *Animal Use Protocol* and requiring immediate ACVS Vet intervention
- Serious threats to the health & safety of personnel or animals
Procedural Non-Compliance

Procedural - Administrative

- **I. Protocol Modification Submission Required**
  - *Protocol Drift:* Procedure is not covered by, or deviates from an approved protocol; however, procedures performed have no negative animal impact (May involve Item IV. below);
  - *Animal Use Exceeds Authorized Numbers;*
  - *Expired Protocol Involving Continued Animal Use - Annual & Full Renewals;*
- **II. Outstanding Personnel Training** – >30 days post-protocol approval
- **III. Incomplete Animal Records**

Procedural – Limited Animal Impact

- **IV. Animal Procedural Adjustment That May Require Protocol Modification Submission**
  - Animal procedures that produce limited distress or pain requiring correction – due to inaccurate or ineffective analgesics, anesthetics, euthanasia methods, or other animal procedures, e.g. extra injections, or inappropriate anesthesia regimes.
  - May involve protocol drift, which requires Protocol Modification form submission (See Item I.)
PAM Core Elements

Non-Compliance Response Processes
Non-Compliance Response Process Flow

Post Approval Monitoring Sources

Protocol Support Veterinarian (PS Vet)

Animal Use Subcommittee (AUS)

Animal Care Governance Steering Committee (ACGSC) / University Council on Animal Care (UCAC)
Procedural & Ethical Non-Compliance Response Flow Charts
Procedural Non-Compliance Response
Steps 1 - 3

1. **Collaborative Issue Resolution** - PS Vet and/or AUS PI Rep contact PI involved in non-compliance and undertake to inform & support timely issue-appropriate resolution.

2. **AUS Issue Resolution Meeting** - Issues not resolved via Step 1 will be forwarded to the AUS Chair or Designate, who will request a meeting with the PI animal user involving ACVS Director, PS Vet, AUS PI Rep to discuss issue resolution.

3. **Full ACC Meeting** - All procedural issues not resolved through Step 2 will be referred to the full AUS and/or the ACGSC.
Ethical Non-Compliance Response – Step 1 - Communication & Immediate Intervention

1.1. PS Vet attempts to communicate with PI/animal user, AUS Chair, ACVS Director and AUS PI Rep.

1.2. Facility Manager or Compliance Officer may provide humane euthanasia, if required.
Ethical Non-Compliance Response – Step 1 - Communication & Immediate Intervention

1.3. The PS Vet works with the ACVS team to:
* Ensure immediate end to objectionable procedure(s) by PI/animal user
* Provide appropriate therapy and relief (humane euthanasia of animal(s) if deemed necessary)
* PS Vet contacts the appropriate OH&S if serious threat to health and safety of personnel suspected

1.4. Facility management/ACVS staff provides PS Vet with:
* Verbal/written action confirmation within 1 business day
* Written report to PS Vet detailing actions taken within 5 business days
Unresolved Issue: Communication, ‘On Hold’ Process & Resolution Meeting

2.1. The PS Vet will inform the AUS Chair, ACVS Director, AUS PI Rep, and the Dean/Director of the PI’s/animal user’s research institute.

2.2. The PS Vet will request that:
- AUS Administrative Officer places the *Animal Use Protocol ‘On Hold’*
- Associated Facility Manager ensures no animal ordering and no animal use will be undertaken by the PI/animal user within the facility
Ethical Non-Compliance Response – Step 2 – Unresolved Issue: Communication, On Hold Process & Resolution Meeting

2.3. The AUS Chair/designate will convene a meeting with the ACVS Director, PS Vet, and AUS PI Rep within 2 business days. The PS Vet will document meeting content.

2.4. The AUS Chair or designate will convey meeting outcomes to the PI/animal user within the facility.
Unresolved Issue: Appeal to AUS

3.1. The PI will be invited by the AUS Chair to explain the rationale to the AUS during an interim committee meeting convened for this purpose.

3.2. The Animal Use Protocol will remain ‘on hold’ until the ethical issue has been resolved, or until the AUS determines the appropriate recourse.

3.3. Senior administration will be informed of meeting results.
4.1. Unresolved or persistent breaches of compliance or threats to the health and safety of personnel or animals that cannot be promptly corrected by the AUS working with concerned animal users and ACVS veterinarians will be referred to institutional senior administration for resolution: the Animal Care Governance Steering Committee, and the University Council on Animal Care.
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