



CCAC National Workshop 2015

Post-Approval Monitoring

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The protocol police... or... ?



NO!

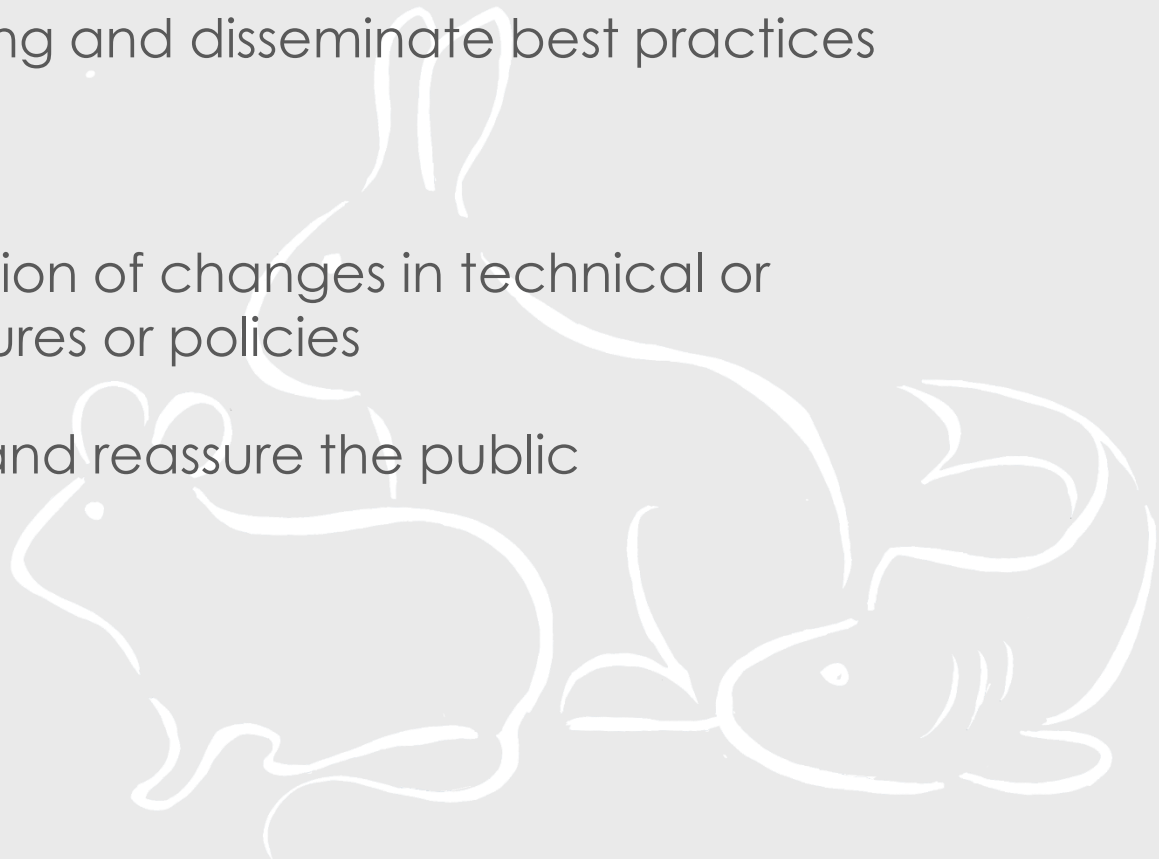
- Described in:
 - CCAC policy statement for: senior administrators responsible for animal care and use programs - Appendix IV
- The CCAC document is quite useful to help guide how we do this!



Principles – Why?

○ Should be Win-Win!

- Ensure animal well-being and disseminate best practices
- Identify training needs
- Facilitate communication of changes in technical or administrative procedures or policies
- Protect the Institution and reassure the public



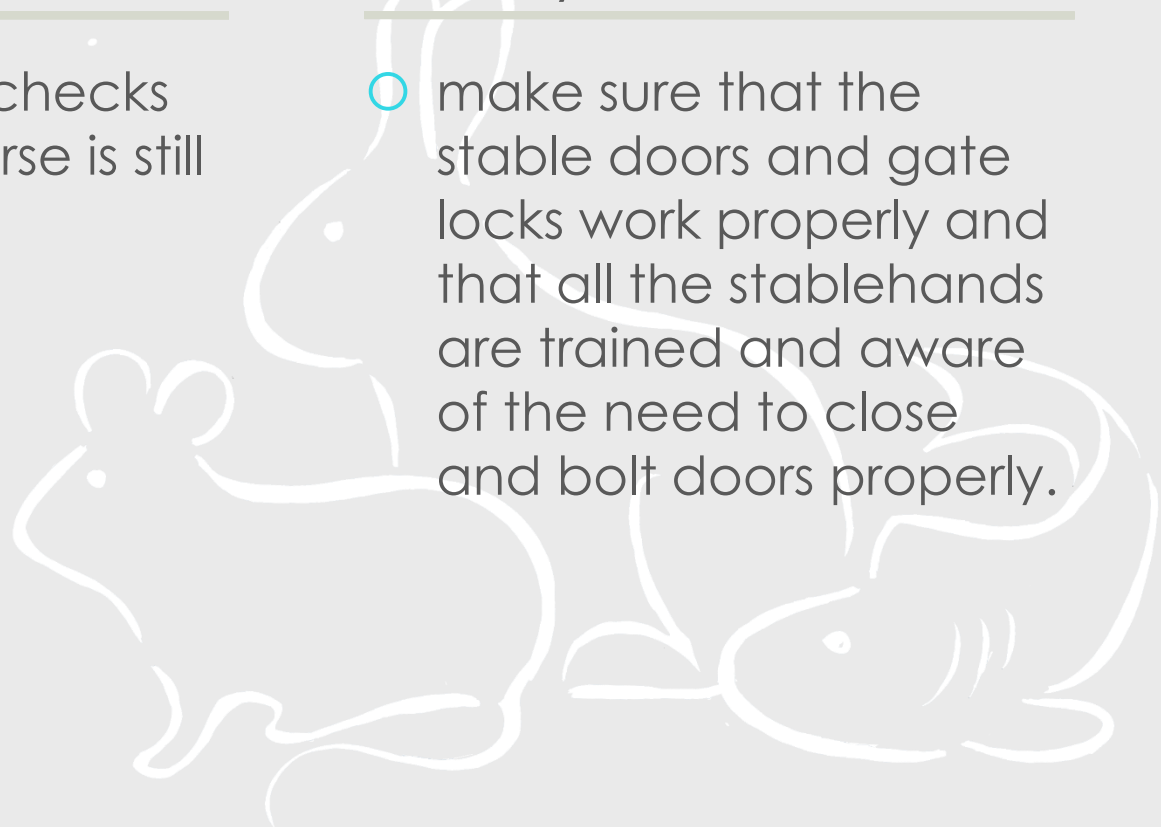
It's about Quality – An “internal audit” process

Quality Control

- doing periodic checks to see that a horse is still in its stable

Quality Assurance

- make sure that the stable doors and gate locks work properly and that all the stablehands are trained and aware of the need to close and bolt doors properly.

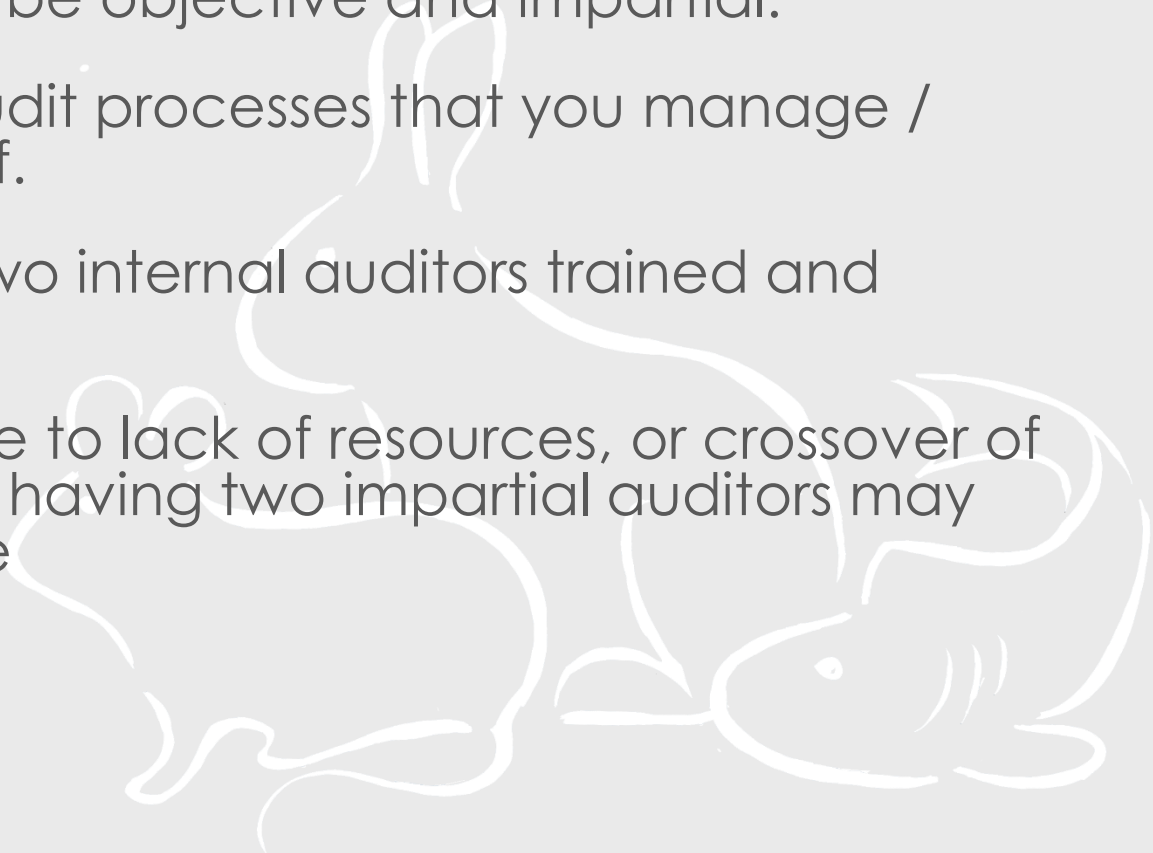


Who?

- Should involve all levels in some way at most institutions
- ACCs, along with animal users, vets, animal care staff and senior administrator
- Many institutions will designate one individual to coordinate, or act as auditor

Who?

- ISO has perfected this!
- Auditor should be objective and impartial.
- You cannot audit processes that you manage / control yourself.
- Best: at least two internal auditors trained and available
- Challenge: Due to lack of resources, or crossover of responsibilities, having two impartial auditors may not be possible



Partners...

The Animal User

- Agrees to undertake protocol as approved in principle by ACC

Animal Care Staff and Vets

- Provide day-to-day assistance and information with respect to animal care and use
- Provide training

Partners...

ACC coordinator or other ACC members

- Assist animal users with their work
- Facilitate the process of amending a protocol when it cannot be successfully continued in practice as originally approved for technical or logistical reasons

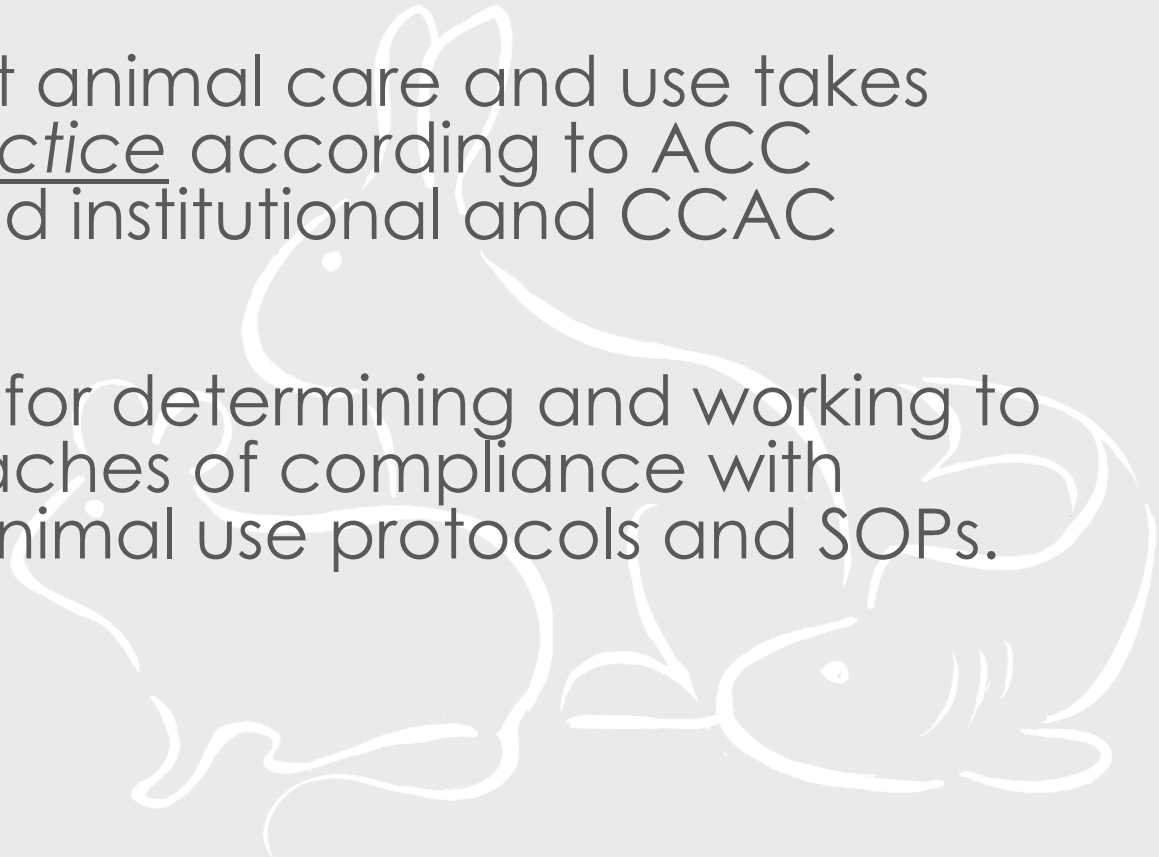
Senior Administrator

- Provide sufficient human and operational resources
- Support and assist as needed in problematic situations



What?

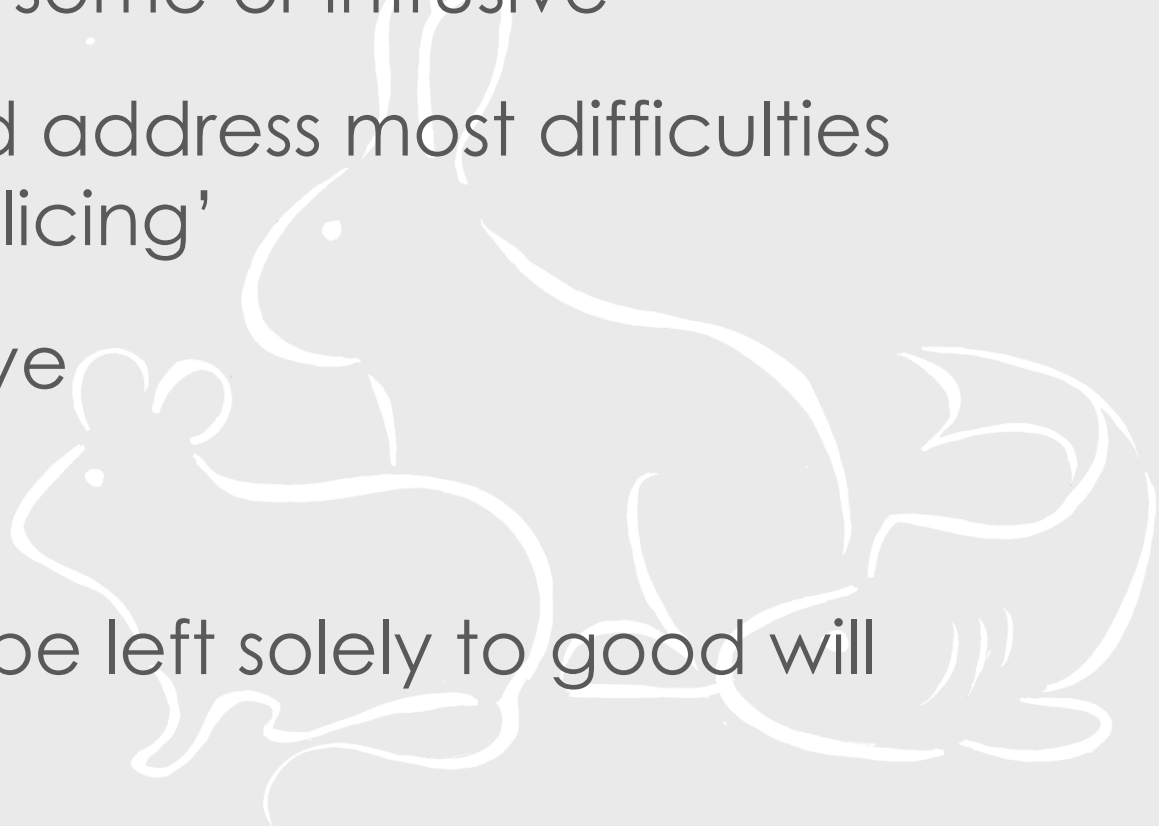
- After ethical review and approval of animal use proposals...
- Ensuring that animal care and use takes place in practice according to ACC decisions and institutional and CCAC standards.
- Responsible for determining and working to correct breaches of compliance with approved animal use protocols and SOPs.



How?

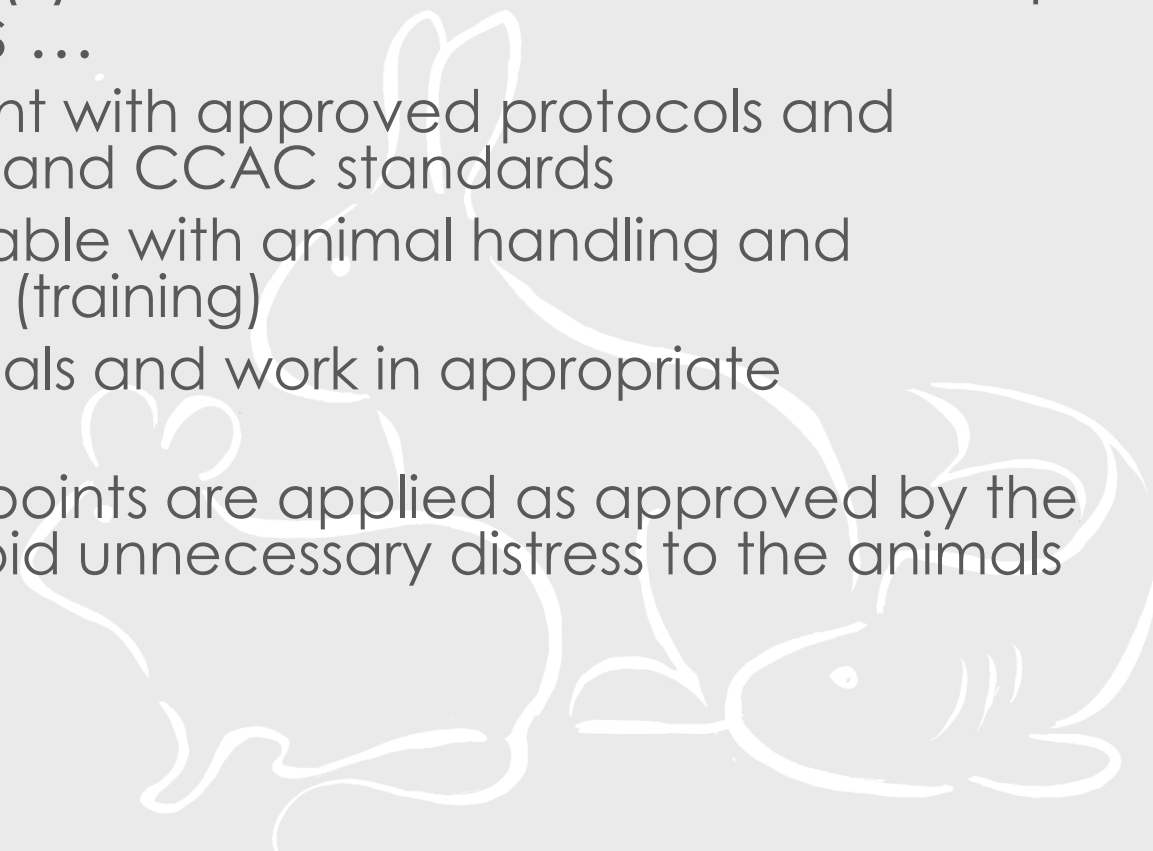
It's all in the approach...

- not cumbersome or intrusive
- identify and address most difficulties without 'policing'
- collaborative
- flexibility
- should not be left solely to good will



How?

- Day-to-day collegial work of the veterinarian(s) and animal care staff to help animal users ...
 - Be compliant with approved protocols and Institutional and CCAC standards
 - Be comfortable with animal handling and procedures (training)
 - House animals and work in appropriate conditions
 - Ensure endpoints are applied as approved by the ACC to avoid unnecessary distress to the animals



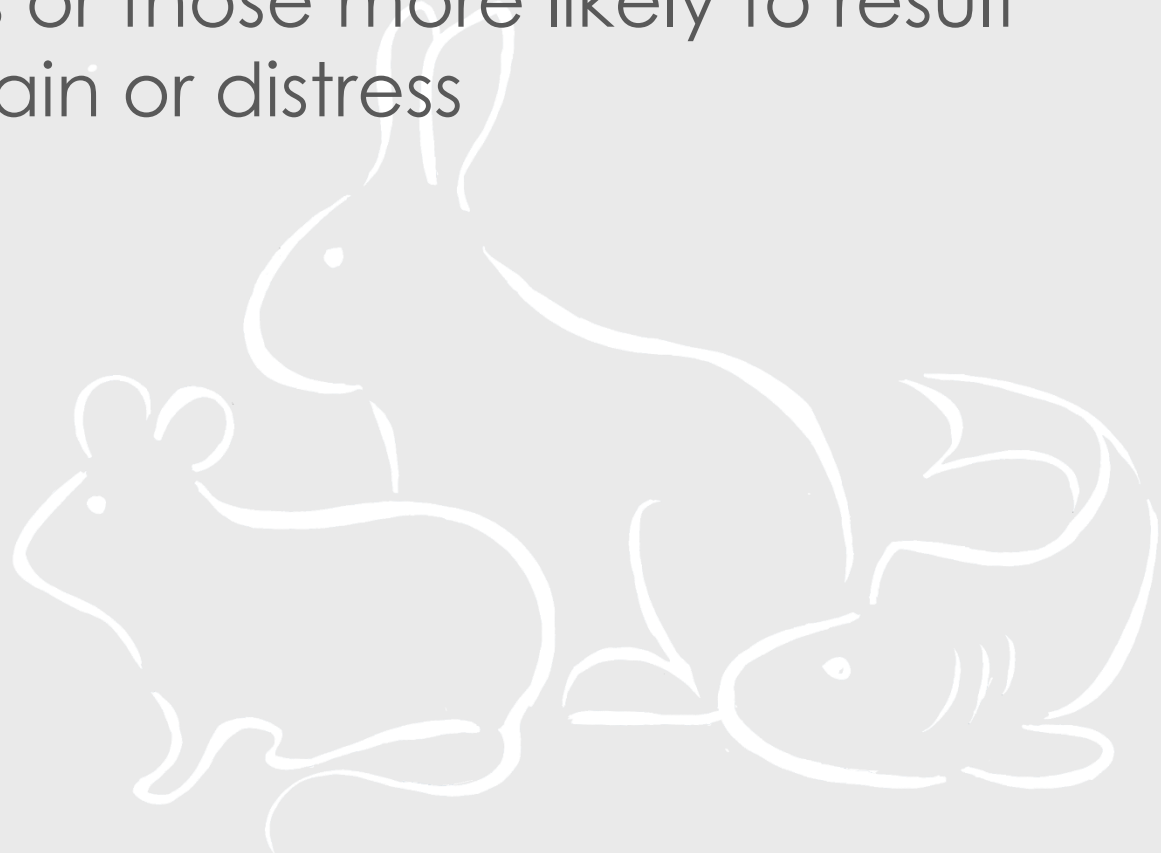
How?

- Assist animal users with their work
- Facilitate process of amending protocol if technical or logistic reasons prevent continuing as originally approved
- Dissemination of best practices, and flexibility where appropriate
- Site visits and discussion – good communication



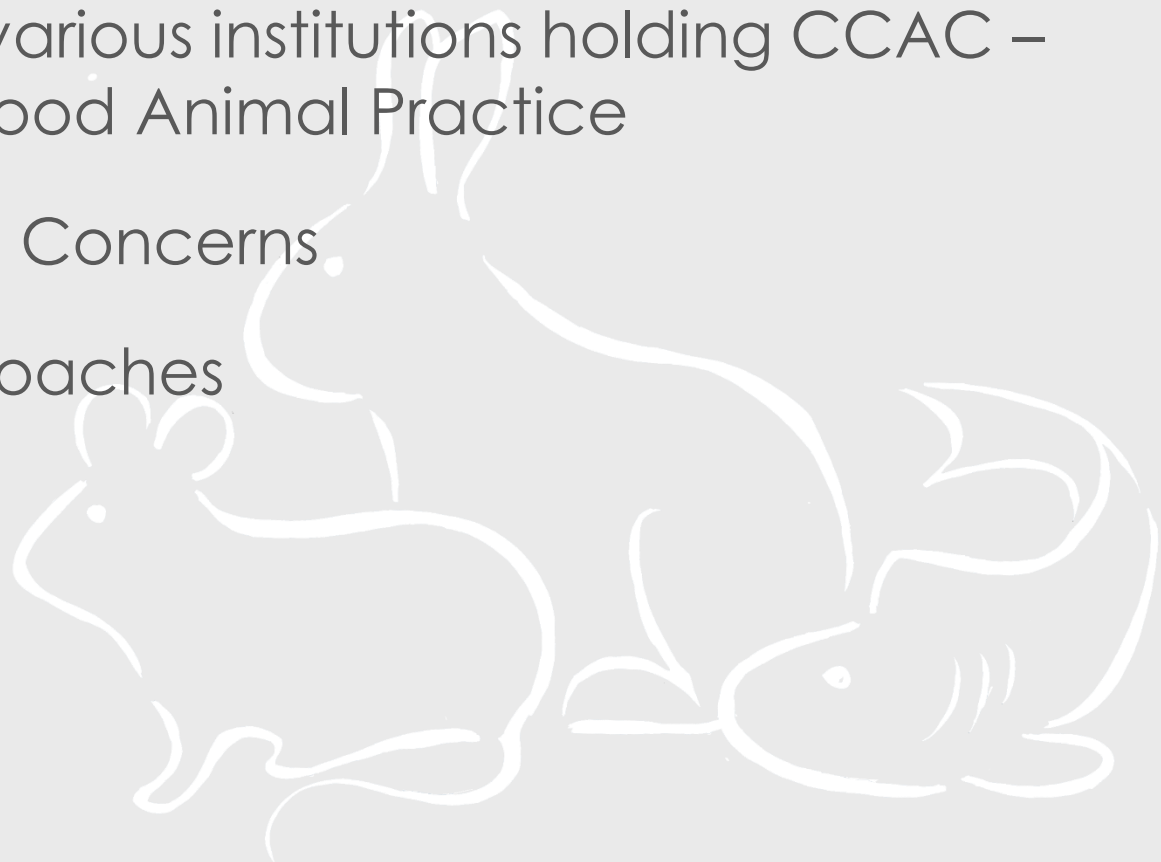
How?

- Careful assistance and follow-up for new procedures or those more likely to result in animal pain or distress
 - Training
 - Re-Training



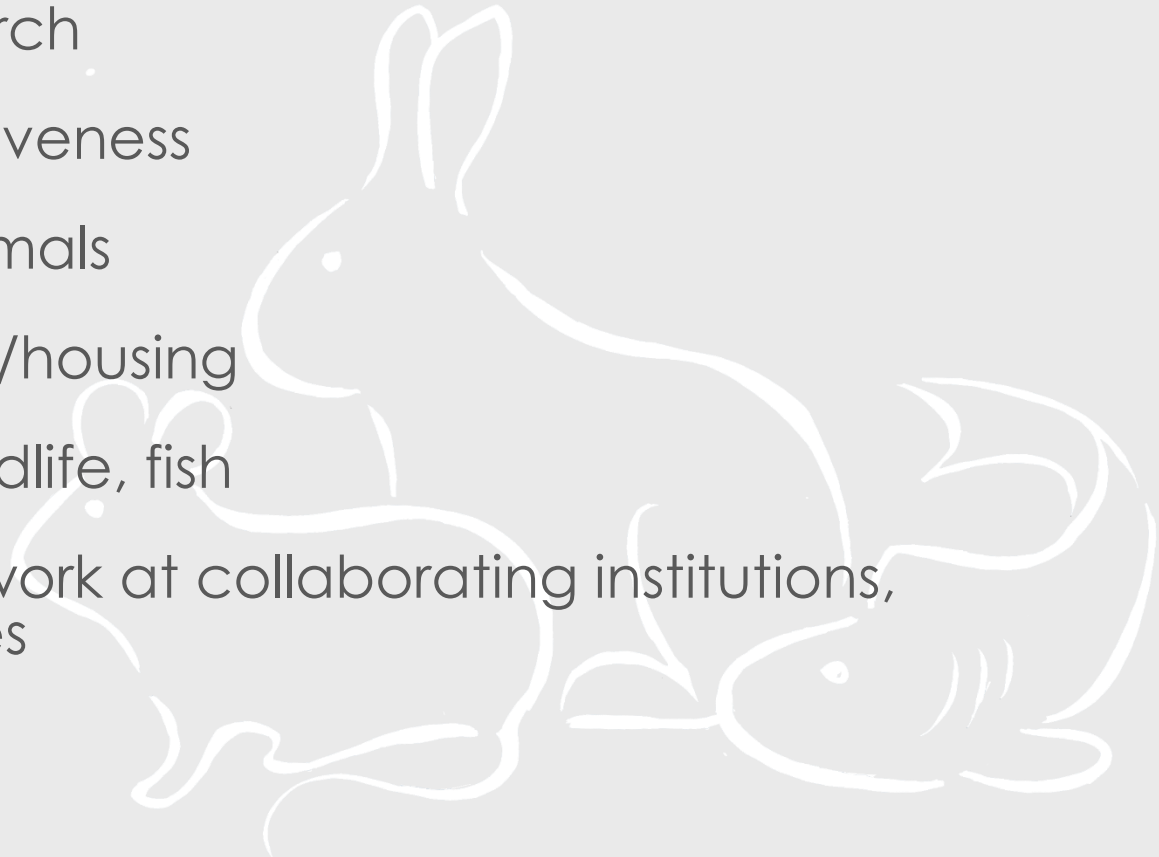
How to do it in “real life”?

- Examples from various institutions holding CCAC – Certificate of Good Animal Practice
- Challenges and Concerns
- Ideas and Approaches



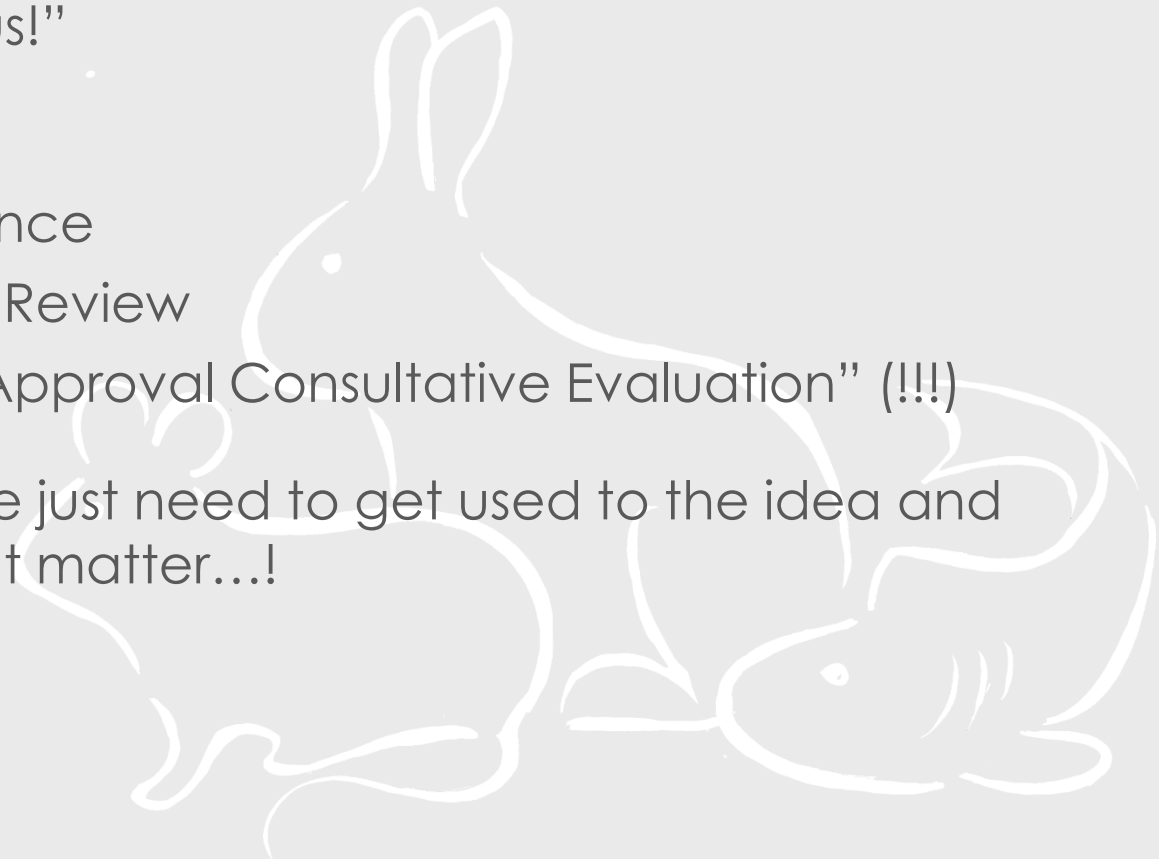
May need different approaches to fit...

- Size of institution
- Numbers of protocols, researchers, staff
- Types of research
- Levels of invasiveness
- Species of animals
- Type of facility/housing
- Field work - wildlife, fish
- Other off-site work at collaborating institutions, private facilities
- Etc!



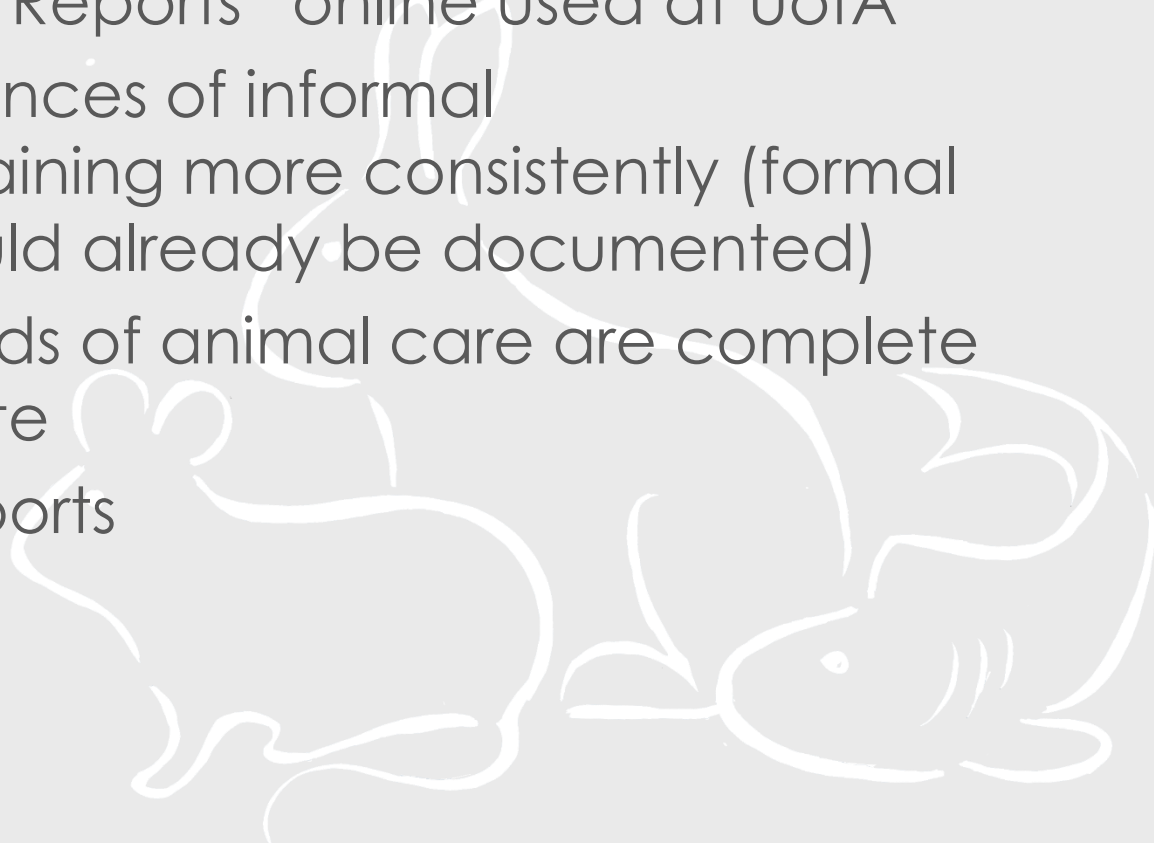
What to call it?

- Challenge: “***Post Approval Monitoring*** sounds too regulatory or police-like!”
- “You don’t trust us!”
- Other options?
 - Quality Assurance
 - Post Approval Review
 - PACE – “Post Approval Consultative Evaluation” (!!!)
- Or maybe people just need to get used to the idea and the name doesn’t matter...!



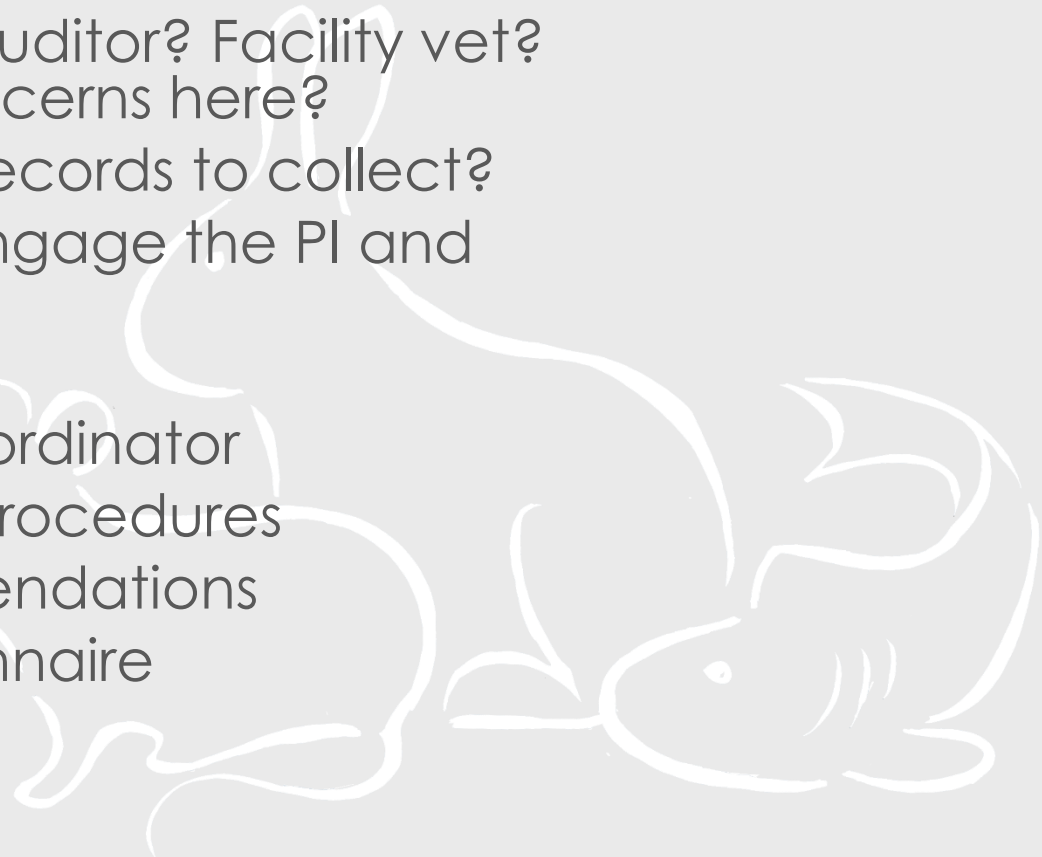
How do we do this?

- Document what we already do
 - Vet consults, rounds, lab visits
 - E.g. “PAM Reports” online used at UofA
 - Record instances of informal training/retraining more consistently (formal training should already be documented)
 - Ensure records of animal care are complete and accurate
 - Incident Reports



How do we do this?

- Define a process for regular, timely review
 - Which protocols to start with or focus on?
 - Who is involved?
 - A coordinator/ auditor? Facility vet? Technician? Concerns here?
 - What documents/records to collect?
 - How to positively engage the PI and staff/students?
 - Pre-visit checklist
 - Meeting with coordinator
 - Review certain procedures
 - Report/recommendations
 - Post-visit questionnaire

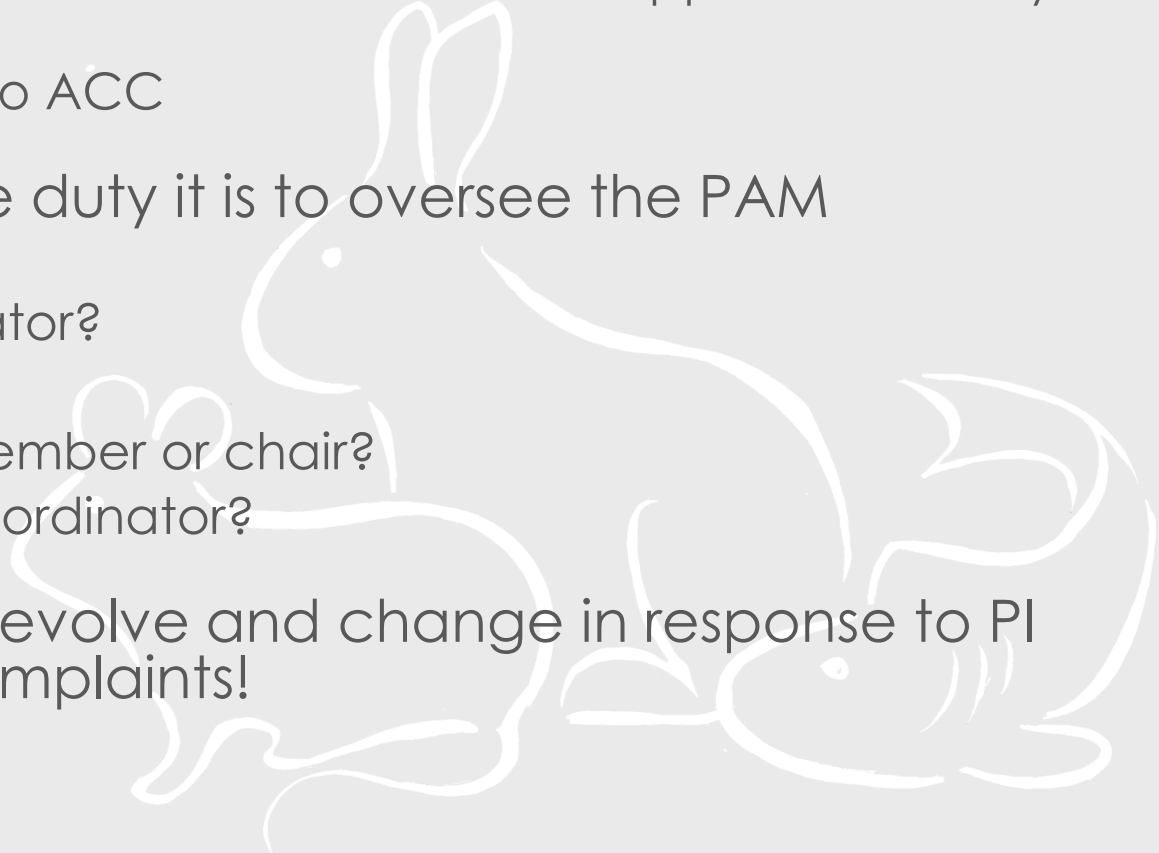


- Reporting back to ACC
- Assistance from Vet and ACC as required, and next steps
- Follow-up, timelines



How do we do this?

- Ensure there is a process to keep ACC informed and involved in any events/issues/changes after approval
 - Amendments submitted for review and approval in timely manner
 - Reports back to ACC
- Is it clear whose duty it is to oversee the PAM process?
 - ACC Coordinator?
 - Vet?
 - Committee member or chair?
 - PAM or QA Coordinator?
- Process should evolve and change in response to PI suggestions/complaints!



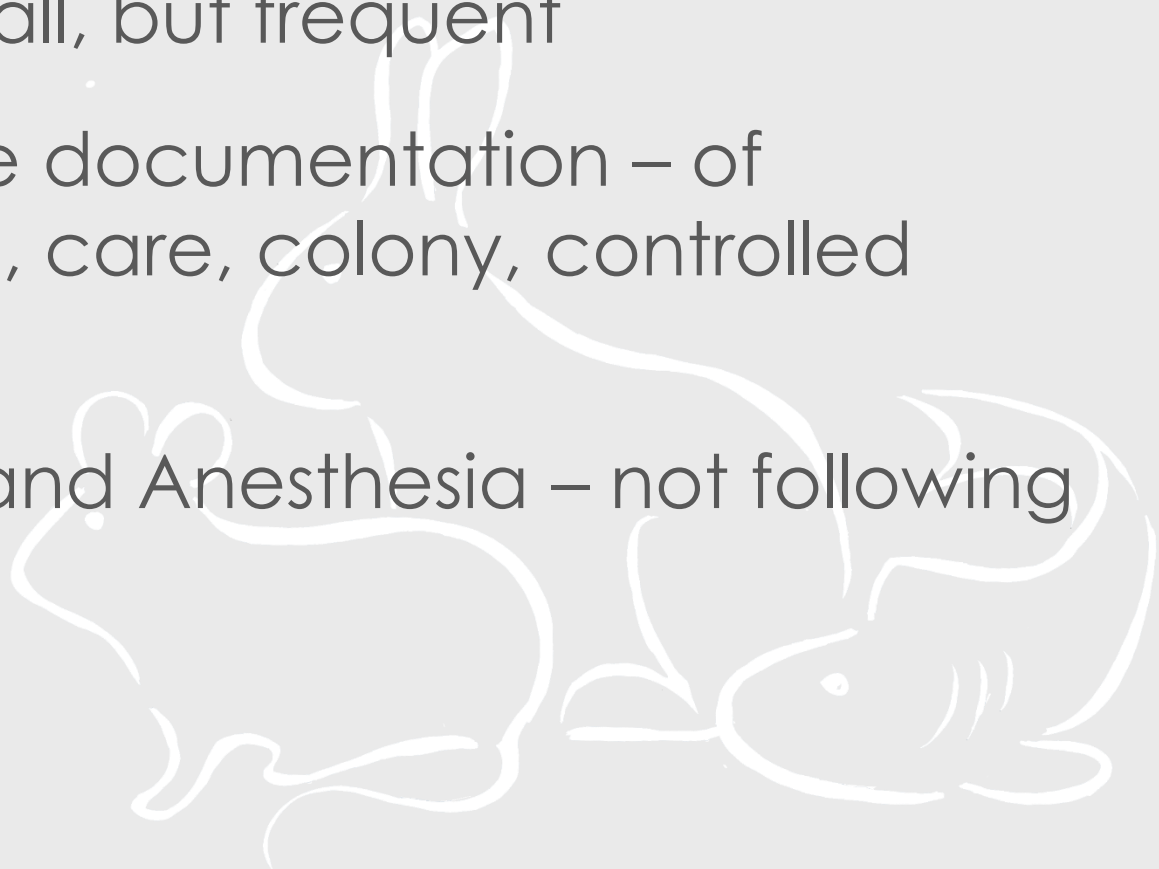
How to describe findings or issues of non-compliance?

- Immediate vs. Major vs. Minor problems
 - Procedural drift
 - Record keeping
 - Training problems
- Is terminology important?
 - Major; Serious; Regular; Minor; Commendatory
 - Immediate; Major; Minor
 - Compliance “with attention”
 - Other terms?



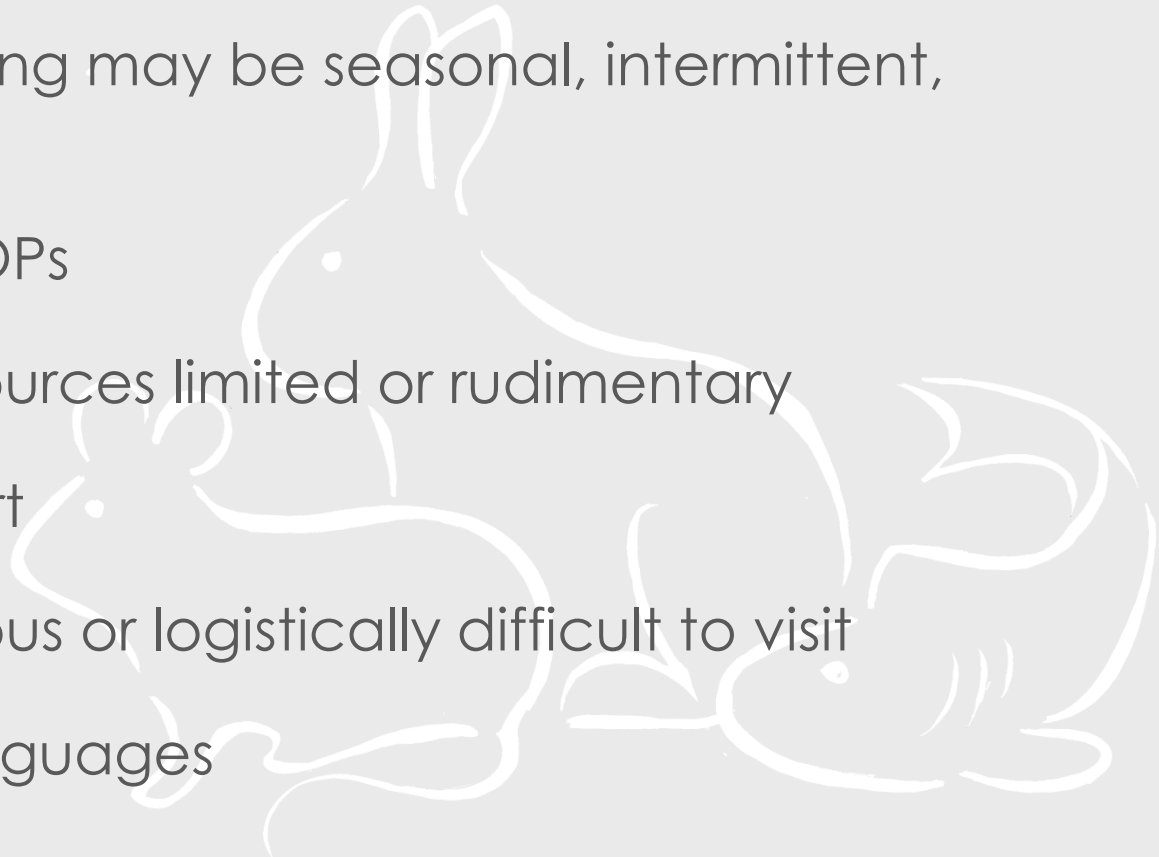
Common Problems?

- Deviation from approved procedures – may be small, but frequent
- Inadequate documentation – of procedures, care, colony, controlled substances
- Analgesia and Anesthesia – not following SOPs



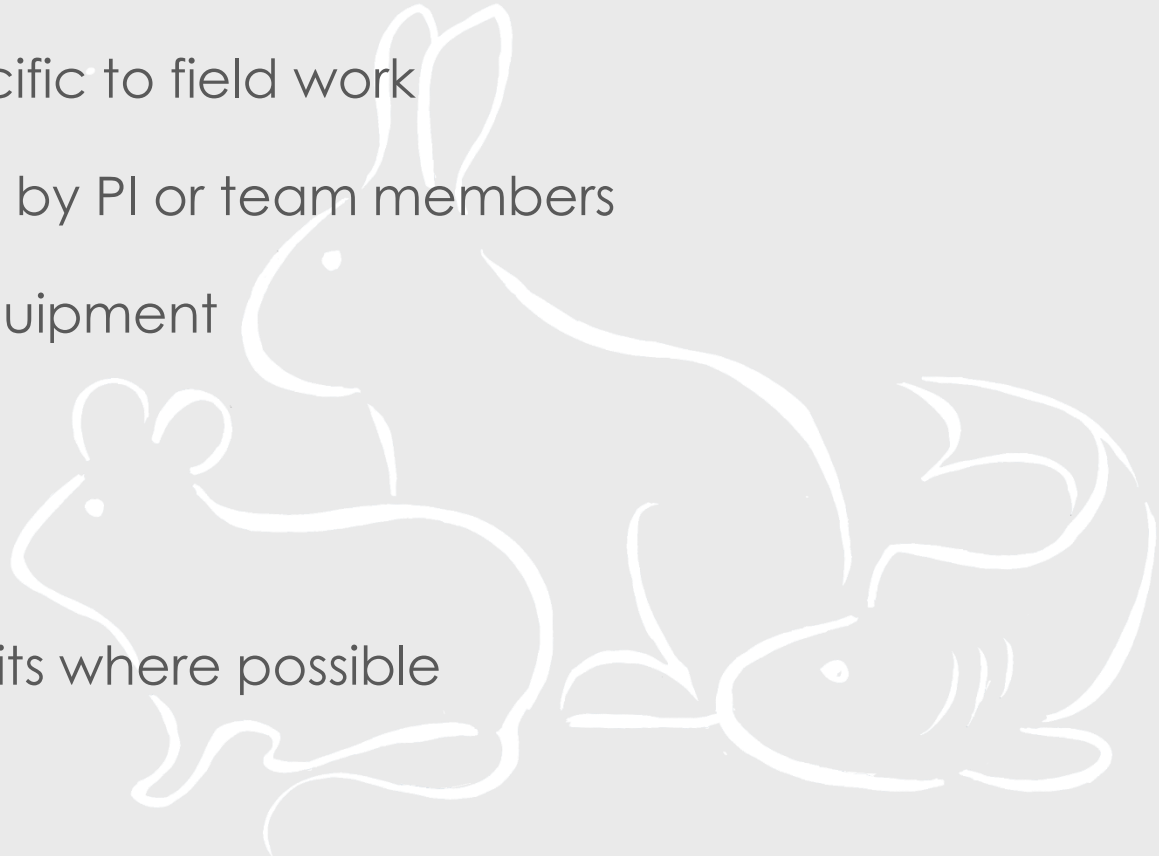
What about Wildlife and Fish?

- Field research
- Distance, many locations
- Capture and handling may be seasonal, intermittent, periodic, or rare
- Lack of common SOPs
- Equipment and resources limited or rudimentary
- PI may be the expert
- Sometimes dangerous or logistically difficult to visit
- Different culture/languages



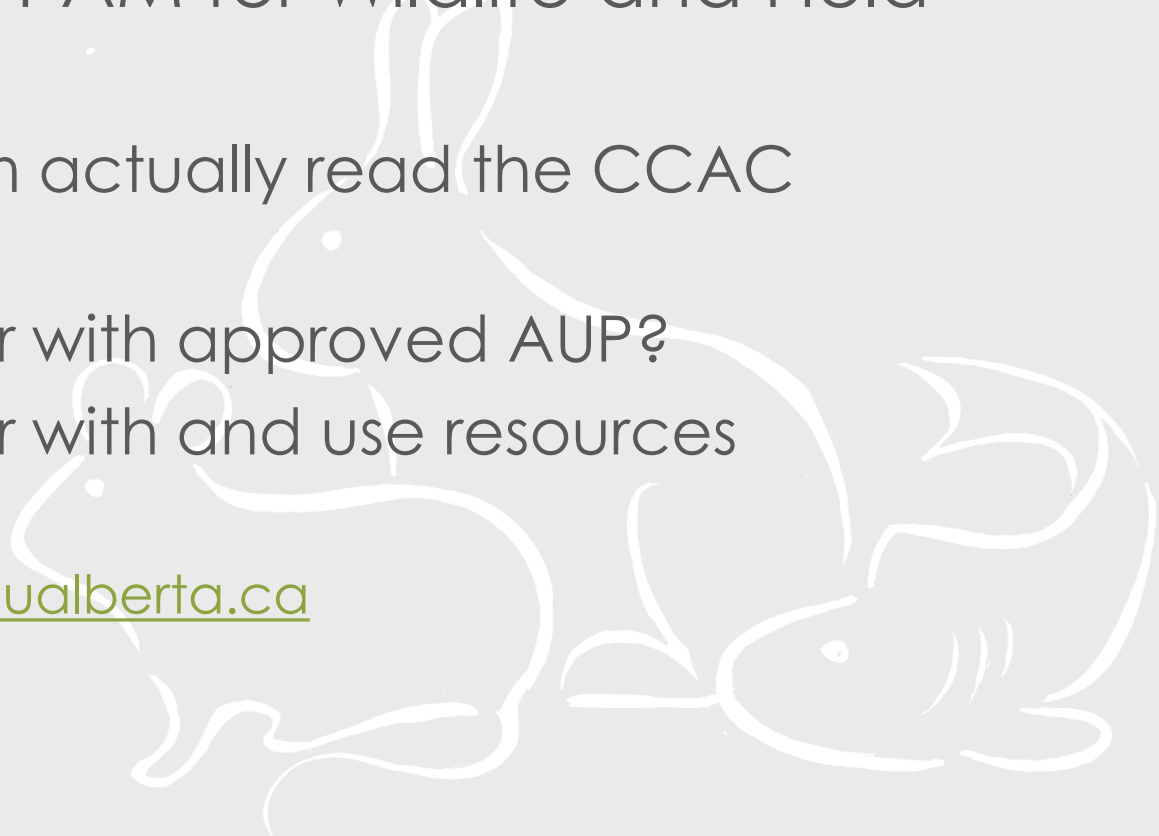
PAM for Field Work

- Meet with PI and team
- Documentation review – SOPs, records; permits
- Questionnaires – specific to field work
- Presentations to ACC by PI or team members
- Demonstrations of equipment
- Photographs
- Videos
- Lab visits; Field site visits where possible



So what challenges do you have?

- How do you do PAM for Wildlife and Field Studies?
 - Has PI and team actually read the CCAC guideline?
 - Are they familiar with approved AUP?
 - Are they familiar with and use resources available?
 - www.fieldoffice.ualberta.ca



So what challenges do you have?

- How do you recruit volunteers (ACC members, others?) to participate to visit labs and document PAM process?



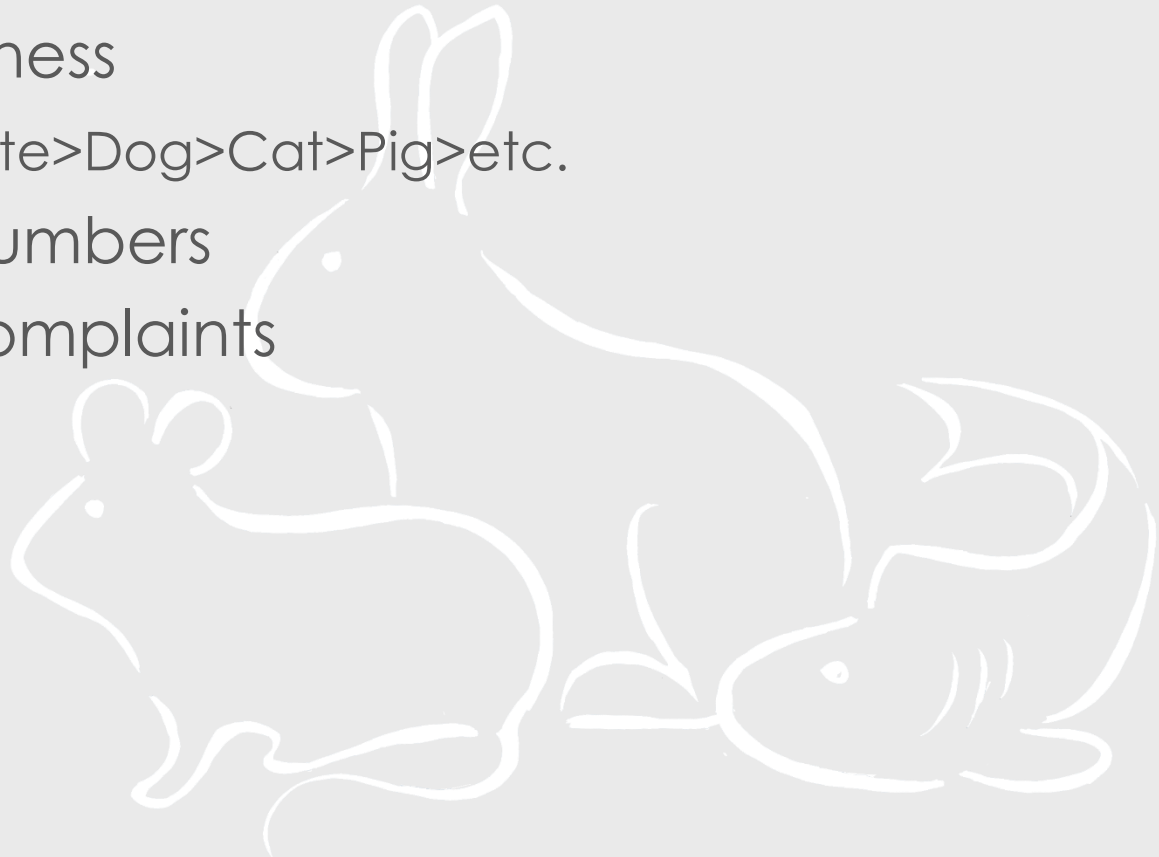
So what challenges do you have?

○ Is work load an issue?



So what challenges do you have?

- How do you select which protocols to focus on?
 - Risk→Invasiveness
 - Species? Primate>Dog>Cat>Pig>etc.
 - High animal numbers
 - Incidents or complaints
 - Random
 - Scheduled



So what challenges do you have?

- Is it difficult to communicate the purpose, goals, or mandate for PAM?



So what challenges do you have?

- How do you deal with non-compliance, partial compliance, or “bare minimum” compliance?



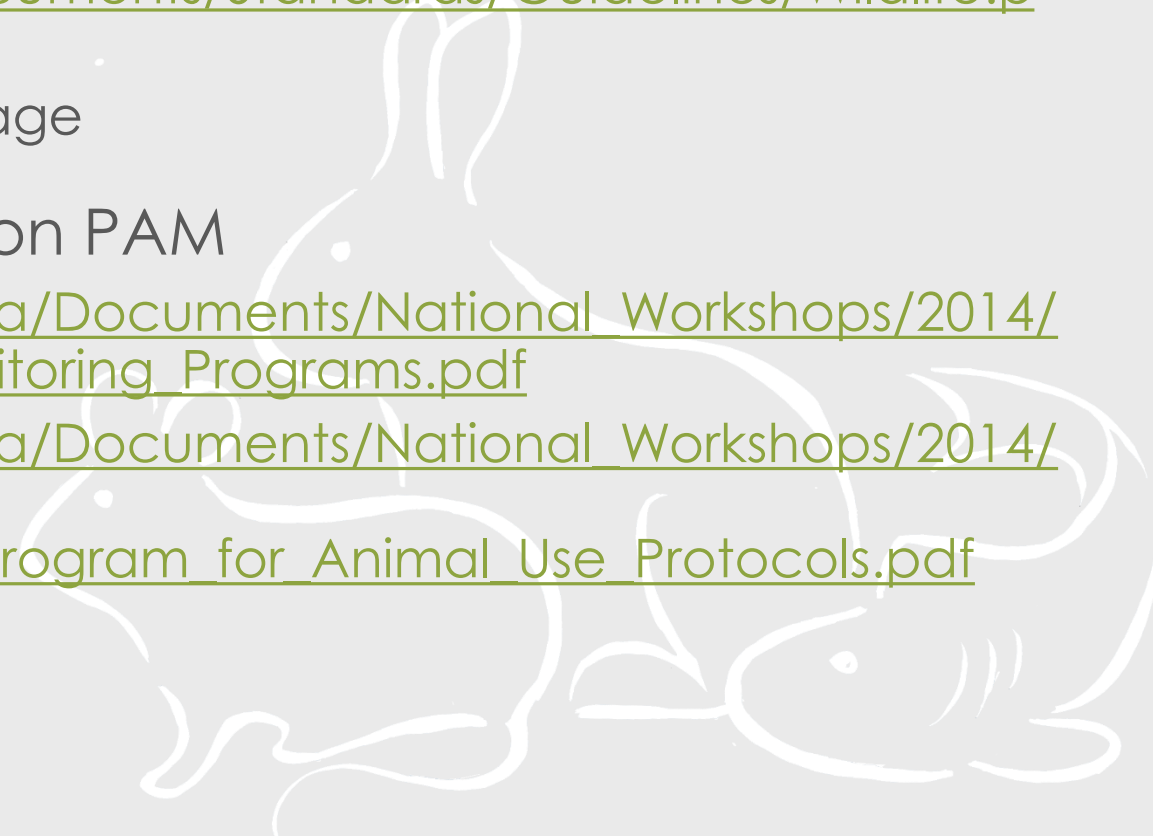
Resources

○ Wildlife Guidelines:

- <http://ccac.ca/Documents/Standards/Guidelines/Wildlife.pdf>
- Also see the FAQ page

○ CCAC Workshops on PAM

- http://www.ccac.ca/Documents/National_Workshops/2014/Post-Approval_Monitoring_Programs.pdf
- http://www.ccac.ca/Documents/National_Workshops/2014/Post-Approval_Review_Program_for_Animal_Use_Protocols.pdf



Credits

- Donna Taylor, PAM Coordinator, UofA
- ACC Coordinators across Canada
- CCAC Staff: Pascale Belleau, Dr. Michael Baar

