

Post-Approval Review Program for Animal Use Protocols

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June 2014



Post-Approval Review Program

for Animal Use Protocols

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PAR program: Creation

- 1) Developed by a working group composed of veterinarians, facility managers, University Animal Care Committee (UACC) Chair (researcher) and Office of Research Ethics staff members
- 2) Tested through 13 pilot visits to a variety of labs across all three campuses
- 3) Revised based on multiple reviews, pilot visits results, and feedback from labs that participated in the pilots
- 5) Approved for launch by the UACC in November 2012
- 4) Ongoing refinement by a PAR advisory group composed of the QAA, a veterinarian, animal facility managers, a researcher, a student, and the UACC Chair



PAR program: Objectives

Support compliance through:

- Ensuring that protocol procedures are performed by labs according to regulatory and institutional requirements;
- Supporting quality research and best practices;
- Maintaining high standards of animal welfare and;
- Facilitating communication between your labs, the Local Animal Care Committees (LACCs), the University Animal Care Committee (UACC), veterinarians, animal care staff, and administrators.



PAR structure



PAR components

The image shows two overlapping forms. The top form is titled 'Post-Surgical Record' and contains fields for PI, Surgeon, Date, Protocol, Surgical Procedure, Emergency Contact, Anesthetic/Dose, Analgesic/Route/Dose, and Surgical Complications. Below these are sections for 'Post-op Care' with a list of analgesics (Buprenorphine, Ketoprofen, Bupivacaine) and routes (Subcutaneous (SQ), By infiltration, Other), and 'Analgesia Administered by' and 'Analgesia Provided by' with date and initial fields. The bottom form is titled 'ILLNESS/HISTORY REPORT' and features a grid of checkboxes for various clinical signs such as 'Hunched posture', 'Rough Hair Coat', 'Abnormal Gait', 'Dehydration', 'Eye problem', 'Problem giving birth', 'Proptosis', 'Incontinence', 'Distended abdomen', 'Malocclusion', 'Ulcerative Dermatitis/skin abrasion', 'Wounds/tearing', and 'Post-procedural complication'.



Animal Welfare Documents and Records
e.g. Animal health consultation and treatment forms, surgical/anesthesia records, training records, etc.

Education
Vets, vivarium staff, and the QAA provide PAR education and retraining in complement to the (pre-approval) formal required training

PAR components



Site Visits

Annual LACC visit, CCAC assessments, annual Ontario Ministry of Agriculture Food and Rural Affairs (OMAFRA) inspection



Quality Assurance Visits

Documented, scheduled visits to labs by the QAA (and veterinary staff as required) to review protocol procedures

QA Visit Process

- QAA acts as ‘eyes and ears’ of LACC and arm’s length reviewer
- Random selection of labs with a priority for invasive studies (e.g. surgical protocols)
- Scheduled visit composed of two parts:
 - a) Introductory discussion
 - b) Procedure review. Not all procedures are reviewed (to avoid duplicate review)
- Your lab is provided with a checklist of regulations prior to the visit (for reference)

QA Visit Process

- Visit includes time for you to ask for clarification or assistance about regulations.
- QA visit report: Summarizes review and related recommendations, with an implementation deadline. Both the researcher and QAA provide input before the report is finalized
- Finalized report is distributed to the relevant LACC and to the researcher
- Visit Frequency: Aim to complete 3-5 visits per month (minimum 3 years to review all 170 labs once), therefore **each lab is visited once every 3-4 years**

QA Visit Approach

YES	NO
1. Contextual interpretation of regulations	1. <i>Black and white interpretation of regulations</i>
2. Collegial and supportive of research	2. <i>Punitive (e.g. aiming to shut down your labs)</i>
3. Reasonable expectations	3. <i>Unrealistic and unreasonable expectations</i>
4. Advisory and consultative	4. <i>Oppressive policing</i>
5. Infrequent and efficient	5. <i>Constant and unexpected monitoring</i>
6. QAA as observer and resource for regulatory support	6. <i>QAA as veterinary/scientific expert</i>

Being a researcher

Research

Students

Grants

Journal articles

Administration

Staff



Budget

Teaching

Conferences

Being an animal researcher

Research

Students

Animal care

Grants

Training

Journal articles

Administration

Animal Use Protocol

Staff

Ethics

Budget

Teaching

Conferences



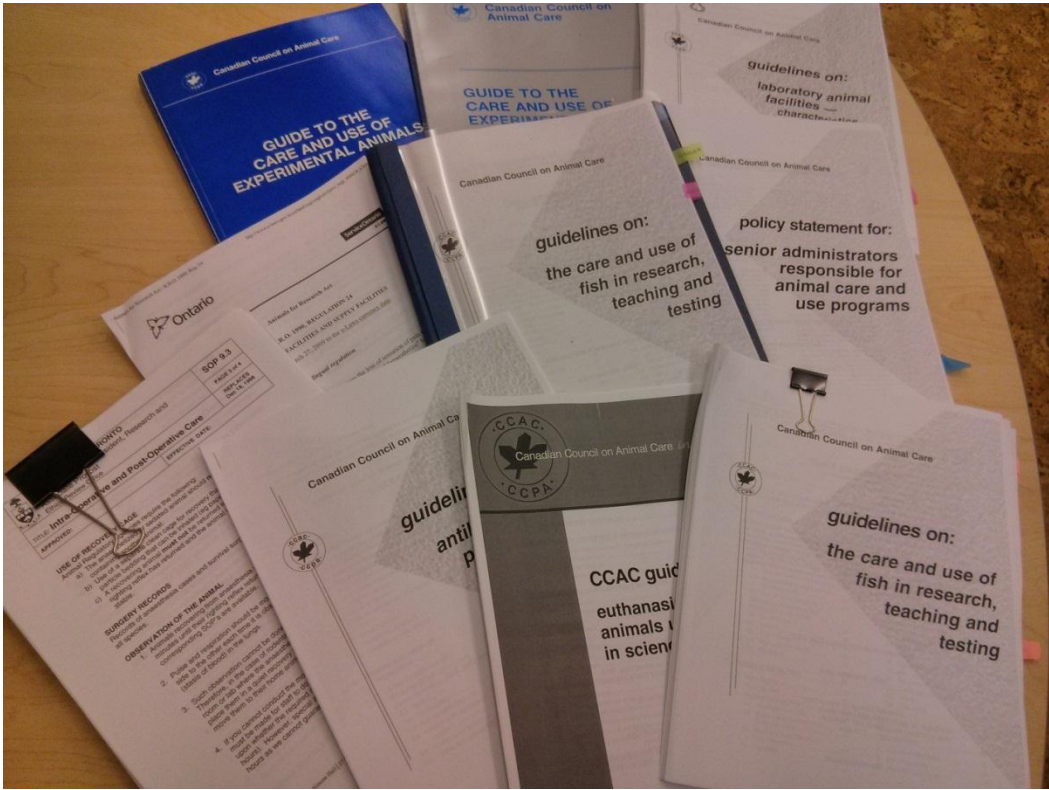
Animal research
regulations

Animal research regulations



**Animal care and use in
research, teaching and
testing**

Animal research regulations



Importance of compliance

Potential consequences of non-compliance:

- NoPosting Status on a Research Fund
- Suspension of protocol work
- Loss of grant funding
- Loss of reputation (individual or institutional)
- Loss of CCAC Certificate of Good Animal Practice
- Loss of OMAF Registration as a Research Facility

Great scott!



PAR benefits

1. Resource and support for navigating animal research regulations
2. Minimize risks to funding and reputation
3. Maintain and increase rapport and communication between your labs, veterinarians, animal facility staff, and administrators
4. Opportunity to review and share best practices (with permission)

Experience to date

- Satisfied with depth of assessment details
- Some (rare but) serious cases found by PAR program
- More intensive follow up oversight, as necessary
- Dedicated resources key to maximizing success
- Metrics to track number/type of infractions
- Well received by majority. Appreciate help/advice

Future directions...

- Target trends identified by PAR visits
 - E.g. improper aseptic technique common → better (refresher?) training
- Focus more on preventative approach
- Better promote availability of resources
- AUP pre-review

Future directions...

- Refresher training/start-up oversight
- Guideline/regulation interpretation
- Veterinary/technical consults
- Improve ongoing communication of standards
E.g. flashy “common mistakes” posters in facilities

Questions?

