Post-Approval Review Program for Animal Use Protocols

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Office of Research Ethics
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

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

5) Approved for launch by the UACC in November 2012
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**

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

Research  Students
Grants  Journal articles
Administration  Budget
Staff  Conferences
Teaching
Being an animal researcher

Research
- Animal care
- Grants

Students
- Training
- Journal articles

Administration
- Staff
- Budget

Ethics
- Teaching

Animal Use Protocol
- 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:

• No Posting 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?