Policy on the Quality Assurance Program (QAP)

From the Canadian Council on Animal Care (CCAC) Terms of Reference for Animal Care Committees (2006)
Through documentation and observation that: “each institution must establish procedures for post-approval monitoring of animal use protocols, and must define the roles and responsibilities of the members of the animal care and use program in the monitoring process…the committee must work with the members of the veterinary and animal care staff to ensure compliance with its decisions and with the conditions set out in approved protocols.”

Objectives of the Quality Assurance Program (QAP):
To facilitate university compliance as dictated by the Animal for Research Act (ARA), Canadian Council on Animal Care (CCAC) guidelines and policies, and Queen’s University policies and Standard Operating Procedures. The QAP is designed to provide support to the research community while ensuring the protection of animal subjects by confirming accurate and consistent UACC approved protocol performance of animal based research in a collegial and unobtrusive manner.

Role of the QAP coordinator:
The role of the QAP coordinator is to:

- Assist Principal Investigators (PI) and their research staff in their continuous efforts to satisfy the University Animal Care Committee (UACC) requirements of compliance and best practice through objective and accurate reports.
- To assess student’s competency following completion of their respective training workshops.

The QAP coordinator will work under the guidance of the University Veterinarian/Director, Animal Care Services and according to the needs and intentions of the University Animal Care Committee. The QAP coordinator serves as the eyes and ears of the UACC, without voting privileges, but with obligations to advocate on behalf of the UACC when interacting with researchers and research associates.

The QAP coordinator observes animal use activity, prepares accurate reports of observations made, provides recommendations for maintaining compliance, assists (if required) in the preparation of correct amendment applications to keep laboratory activities compliant with approved protocols, and (if required) provide training for non-compliant activities.

The following activities are subject to review:
- Active protocols, regardless of level of invasiveness, but priority given to those protocols which are level D and E
- Suspected cases concerning animal welfare issues and allegations of non-compliance
- Any protocol as selected by the UACC to require monitoring (i.e. new procedures)
- Off campus (QUBS and field studies)

Campus activities will be reviewed by the QAP coordinator by systematic review of active protocols, targeted review or competency review as defined below.

Systematic Protocol Review:
Active Protocols or animal procedures will be systematically reviewed, with priority given to protocols with level of invasiveness D and E.

- The QAP coordinator will give advance notice of announced visits to the Principal Investigator via email outlining which protocol is undergoing review. The Principal Investigator will be asked to
Policy on the Quality Assurance Program (QAP)

• respond within five (5) business days with three different dates which the protocol's activities will take place and who in the lab will be in attendance.

• The QAP coordinator will then confirm the date and will use a standard UACC approved Observation Report Form to facilitate documentation of the visit (QAP Observation Report Form). At the end of the visit, the coordinator will discuss with staff in attendance the findings. The QAP Coordinator will prepare a draft report which will be shared with both the UACC Chair as well as the University Veterinarian/Director if there are concerns regarding any observations made. Once the report has been reviewed by both parties, a final version of the report will be sent to the Principal Investigator as well as filed within their protocol.

• If the protocol is deemed in full compliance both the UACC Chair and University Veterinarian/Director do not need to review the report prior to being sent to the Principal Investigator, however all QA reviews will be presented to the committee at the following UACC meeting.

• The UACC reserves the right to request a follow up visit.

Targeted Protocol Review:
When there is an allegation of non-compliance, or an incident report has been filed
• The QAP coordinator will contact the Principal Investigator and mentioned lab staff to request a time which is convenient for all parties to observe/discuss the activity/issue
• The same Observation Report Form described above will be used and personnel will be given a chance to look over the conclusions drawn from the visit before a final report is sent to the University Veterinarian/Director and UACC Chair for response. This form will be kept on file with the protocol.
• The UACC reserves the right to request a follow up visit.

Competency Review:
Student strengths and weaknesses are assessed during training workshops. Any areas of concern are communicated to both the student and the Principal Investigator upon completion of workshops and arrangements are made for further training.

• To assess how students continue to perform following workshops (approximately 3-4 weeks afterwards), the QAP Coordinator will schedule a time to observe activities associated with their studies.
• In instances where a student performs to a standard where animal welfare may be compromised, they do not follow the approved protocol or they are engaged in procedures which were not covered in the workshops, the student will be asked to stop the procedure immediately. Students will be directed to attend further training sessions and the Principal Investigator will notified of the recommendation.
• Both the UACC Chair and University Veterinarian/Director will be contacted and reserve the right to request a follow up visit.

PI Directed Review:
Researchers whose projects take them into areas which are deemed less accessible will be invited to discuss their methods with the QAP coordinator when they have returned to campus.
Policy on the Quality Assurance Program (QAP)

UACC Reporting:
Prior to the UACC meeting, the QAP Coordinator will meet with the University Veterinarian / Director, Animal Care Services to review the observations from the previous month. Observations will be reported to the UACC using a written trend report. In addition, a copy of the report as submitted to the PI will be made available to the committee.

- Written Trends Report: The following information will be included within the trends report:
  - A list of PIs for which no deficiencies were noted;
  - Unapproved personnel performing approved procedures;
  - Incorrectly labeled cage cards;
  - Minor procedural deviations to approved procedures that although a deviation follows UACC policy and did not change the outcome or goal of the study, nor did the deviation have a negative impact on the general welfare of the animals; and when the PI has, upon notice by the QAP coordinator, returned to the approved protocol and has terminated further use of the deviated procedure until submission and approval of an amendment for the observed modification;
  - A list of deficiencies that were noted during the observations and the necessary corrections.

- QAP Visit Request Follow Up
  - The initial request letter will be followed by one reminder (2 weeks later) and communication from the UACC will take place if no response is received within another 2 weeks (4 weeks from initial letter).

Definitions of Terms

Full Compliance
Granted when procedures appear to follow approved practices. No discrepancies are found during the observation visit; animal welfare, lab practices and conditions are not a concern.

Compliance (Attention Required)
Granted when minor discrepancies are found during the visit which does not cause direct concern to the animal(s); but still need to be addressed. These issues are documented in a formal conclusion letter, but are usually addressed and/or corrected during the visit or within days of the Principal Investigator receiving the final observation report.

Examples: Protocols that have not been altered to reflect new institutional policies, records of training not entered in protocol, inappropriate Personal Protective Equipment (PPE) in the lab.

Non-Compliance (Minor)
Granted when deficiencies are observed which do not necessarily cause immediate pain or distress to the animal, but does deviate from the approved protocol. These concerns could be conveyed during the visit and are documented in a formal conclusion letter. A response of action from the Principal Investigator must be specified in writing and/or electronically within 24 hours of receiving the report, which will be delivered via email and campus mail.
Policy on the Quality Assurance Program (QAP)

Examples: Any procedural drift from approved protocol on a live animal that does not impact animal welfare, failure to list personnel on protocol who are working with animals, failure of staff to attend available mandatory training sessions, inadequate documentation of records, use of expired drugs (non-analgesics/anaesthetics), failure to don appropriate PPE within the facility, over crowded cages.

Non-Compliance (Major)
Granted when deficiencies observed can cause pain or distress to the animal. Depending on the situation, these issues can be relayed during visit or after consultation with the University Veterinarian. Immediate action by the Principal Investigator and or lab staff must be taken. Concerns will be documented in a formal letter. A formal response from the Principal Investigator must be submitted in writing and/or electronically within 24 hours of receiving the report which will be delivered via email and campus mail.

Examples: Severe morbidity (e.g. pain and/or distress, moribund state, ignoring clinical endpoints, inadequate euthanasia techniques or methods).

Documentation
Outcomes of QAP visits are documented within the Compliance section of the Topaz Elements Animal Use Protocol form. Information included is:

- date of visit
- status assigned (Full Compliance, Compliance (Attention Required), Non-Compliance (Minor), Non-Compliance (Major))
- QAP deficiencies
- QAP follow-up (courses of action).

Note that deficiencies fall within (but are not exclusive to) these broad categories:

- Animal Welfare
- Aseptic Technique
- Cage/Animal Transportation
- Controlled Drug Storage
- Documentation
- Drug Labelling
- Expired Drugs
- Occupational Health & Safety
- Post-Surgical Care
- PPE
- Protocol Access
- Protocol Administrative
- Protocol Drift
- Sharps Disposal
- Standard Procedure Assignment
Post-Approval Monitoring
Quality Assurance Visit Report

Visit date and location:
Principal Investigator:
Protocol number:
Protocol expiry date:
Protocol title:
Species:
Lab members present (full name and affiliation):
QAP personnel present:

General Protocol:
Do all lab members have easy access to the protocol within Topaz?  Yes ☐  No ☐  N/A ☐
Are personnel demonstrating procedures listed on the protocol, and appropriately trained?  Yes ☐  No ☐  N/A ☐
Have personnel read the protocol and demonstrate accurate knowledge of the protocol?  Yes ☐  No ☐  N/A ☐

Notes:
### Animals:
Are the animal species (and strains if listed) used consistent with those listed in the protocol?  
- Yes ☐  No ☐  N/A ☐

Is the number of animals housed appropriate for the cage size?  
- Yes ☐  No ☐  N/A ☐

Do phenotypes have any special characteristics (dwarfed limbs, hair loss, abnormal behaviours, neurological issues, etc.)?  
- Yes ☐  No ☐  N/A ☐

Have there been any unusual colony issues (mortality, morbidity, cannibalism, dystocia)?  
- Yes ☐  No ☐  N/A ☐

### Breeding:
Is breeding information recorded (date of pairing, DOB, number of pups, weaning date, etc.)?  
- Yes ☐  No ☐  N/A ☐

Are animals weaned at the appropriate age?  
- Yes ☐  No ☐  N/A ☐

Are pups genotyped in accordance with the SOP?  
- Yes ☐  No ☐  N/A ☐

Are the breeding pairs housed as per the UACC Policy on Colony Management?  
- Yes ☐  No ☐  N/A ☐

### Procedures (General):
Are the procedures performed consistent with those described within the approved protocol?  
- Yes ☐  No ☐  N/A ☐

Are animals handled according to the methods taught in training, keeping pain and distress to a minimum?  
- Yes ☐  No ☐  N/A ☐

Are all procedures accurately documented on the cage card?  
- Yes ☐  No ☐  N/A ☐

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Notes:
Does the protocol on the cage card match the protocol number? Yes ☐ No ☐ N/A ☐

Are personnel wearing appropriate PPE? Yes ☐ No ☐ N/A ☐

Are biohazard SOP’s and policies being followed? Yes ☐ No ☐ N/A ☐

**Anesthesia and Drugs:**
Are anesthetics used consistent with those described within the approved protocol? Yes ☐ No ☐ N/A ☐

Are all compounds administered within their expiry dates? Yes ☐ No ☐ N/A ☐

Is the anesthetic depth appropriate for the procedure? Yes ☐ No ☐ N/A ☐

Is the anesthetic depth appropriately monitored? And by what means? Yes ☐ No ☐ N/A ☐

Is inhalant gas scavenged properly? Yes ☐ No ☐ N/A ☐

Is the frequency of monitoring during recovery adequate? Yes ☐ No ☐ N/A ☐

Is there an appropriate recovery area for this species? Yes ☐ No ☐ N/A ☐

Do all controlled drugs have a valid exemption? Yes ☐ No ☐ N/A ☐

Is the controlled drug log maintained and up-to-date? Yes ☐ No ☐ N/A ☐

Is the anesthetic machine and vaporizer serviced and calibrated? Yes ☐ No ☐ N/A ☐

**Surgical:**
Is the surgery performed in a location approved by the UACC? Yes ☐ No ☐ N/A ☐

Does the surgeon wear sterile gloves during the procedure? Yes ☐ No ☐ N/A ☐

Is surgical attire worn (mask, cap, clean gown, shoe covers)? Yes ☐ No ☐ N/A ☐

Notes:
Are the surgical instruments sterilized? Yes ☐ No ☐ N/A ☐

Is an appropriate method of sterilization used for instruments between surgeries? Yes ☐ No ☐ N/A ☐

Is the surgical site prepped using aseptic techniques? Yes ☐ No ☐ N/A ☐

Are sterile drapes used? Yes ☐ No ☐ N/A ☐

Is heat therapy provided to maintain body heat? Yes ☐ No ☐ N/A ☐

Is the animal receiving correct fluid therapy dose? Yes ☐ No ☐ N/A ☐

Does the method of wound closure correspond to the protocol? Yes ☐ No ☐ N/A ☐

Is the analgesia regime (drug, dose, frequency, route, duration) consistent with the protocol? Yes ☐ No ☐ N/A ☐

Is a surgical logbook maintained? Yes ☐ No ☐ N/A ☐

Is the post-surgical care accurately documented (weight, urine, defecation, fluid and food consumption, wound healing) Yes ☐ No ☐ N/A ☐

Is the removal of sutures or staples consistent with the protocol and Removed at an appropriate interval (7-14 days)? Yes ☐ No ☐ N/A ☐

Is the surgical procedure recorded on the cage card? Yes ☐ No ☐ N/A ☐

Notes:

**Euthanasia and Endpoints:**

Does the method of euthanasia correspond with the protocol? Yes ☐ No ☐ N/A ☐

How is mortality confirmed (secondary method)?

If a physical method is used, is anesthesia administered prior? Yes ☐ No ☐ N/A ☐

Where is the euthanasia performed?
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are remains disposed of promptly and correctly?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Are lab members familiar with protocol endpoints (study or humane)?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Are animals euthanized when an endpoint is reached?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Are animals secluded from cage/ roommates for the euthanasia?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
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</tbody>
</table>

**Notes:**

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**General (husbandry, transportation, etc.):**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
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<tbody>
<tr>
<td>Is a daily log maintained for the room (temperature, humidity, etc.)</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Is health monitored daily?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
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<tr>
<td>Are any medications/ fluids stored in the colony room within expiry?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
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<tr>
<td>Is there sufficient species-specific enrichment?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
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<tr>
<td>Is there sufficient PPE within colony and technical rooms?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
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<tr>
<td>Is there sufficient disinfectant within colony and technical rooms?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Are cages transported in an appropriate manner to the laboratory?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
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<tr>
<td>Are animals provided with potable water within the lab?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
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**Notes:**

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**Additional Aquatics and Wildlife Questions:**

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<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
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<tbody>
<tr>
<td>Are records of feeding and feeding behaviour kept?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Is the housing water quality as described in the protocol?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
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<tr>
<td>Question</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
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<td>Is the water quality monitored regularly (temperature, pH, DO,</td>
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<td>ammonia/nitrite levels)?</td>
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<tr>
<td>Are water/ambient temperature appropriate for the species?</td>
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<tr>
<td>Is health monitored daily?</td>
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<td>Is there sufficient disinfectant within colony and technical rooms?</td>
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<td>Are tanks transported in an appropriate manner to the laboratory?</td>
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<td>Are steps taken to avoid contamination between tanks?</td>
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<tr>
<td>Are electrical components protected from moisture?</td>
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**Surgery:**

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<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
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<tr>
<td>Are gloves pre-moistened?</td>
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<td>Is the surgical site appropriately prepared (removal of debris, etc.)?</td>
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<td>Is the skin kept moist and are gills provided with oxygenated water?</td>
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<td>Is the duration of surgery within the length of time the animal can</td>
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<td>be out of water?</td>
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<td>Has the person performing the task been appropriately trained and is</td>
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<td>using safe methods of handling?</td>
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<td>Are the methods of capture consistent with the approved protocol?</td>
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<td>Are the methods of banding consistent with the approved protocol?</td>
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<td>Question</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
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<td>Are the methods for tissue collection consistent with the protocol?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
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<tr>
<td>Are the methods for blood collection consistent with the protocol?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
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<tr>
<td>Are the described timeframes for capture/release consistent with the protocol?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
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<tr>
<td>Are transmitters used?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
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Notes: