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:

1. 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.
2. 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, poster 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 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.

When there is a case of serial non-response from the Principal Investigator (and laboratory):
• The QAP Coordinator, accompanied by a minimum of one other committee member, may visit the lab, technical room, or colony room impromptu.
• The same Observation Report Form described above will be used. The visit will be held in a standard fashion with observation of procedures followed by discussion with the lab member(s) and a formal letter summarizing findings forwarded to the Principal Investigator (and the UACC Chair and University Veterinarian).
• Circumstances of serial non-response will be assessed on a case-by-case basis. Impromptu visits will only be initiated by the Training Coordinator with full UACC committee approval.

Poster Review:
Undergraduate and Graduate posters may be assessed for compliancy to the Animal Use Protocol. This approach will be used at the instruction of the Chair and the University Veterinarian, and will be a cursory review of the project. The Quality Assurance Program aims to capture off-site and collaborative research with this tool. Poster Coordinators will be contacted by the Quality Assurance Coordinator in advance to advise students of this potential review process.

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.

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.

**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 fourteen days of receiving the report, which will be delivered via email.

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 (with the exception of analgesics and anesthetics), failure to don appropriate PPE within the facility, over-crowded cages, aseptic technique (minor deficiencies).

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 seven days of receiving the report which will be delivered via email.

Examples: Severe morbidity (e.g. pain and/or distress, moribund state, ignoring clinical endpoints, inadequate euthanasia techniques or methods), unapproved procedural drift that escalates the Level of Invasiveness of the research project(s) to the degree that it impacts animal welfare, aseptic technique (major deficiencies), use of expired analgesics/anesthetics.

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 Assignation