1. Procedures for the Use of Animals

1.1) All research and teaching at Queen's University involving animals that are housed in University facilities, on private farms, collected in the wild, or held in facilities other than those of the University (institutions not necessarily assessed by the Canadian Council on Animal Care) requires prior approval of the University Animal Care Committee (UACC). The UACC is responsible for overseeing the work carried out by all members of Queen's University who use animals for research, teaching or testing.

   a) Therefore, a Queen’s Principal Investigator (PI) who wishes to carry out animal-based work within a host institution’s facilities must also submit an animal use protocol to the UACC. Both institutions must approve the protocol before commencement. Researchers from other institutions who apply to use the Queen’s University Biological Station (QUBS) or another Queen’s animal care facility must provide the UACC with copies of their home approved protocols for UACC approval. All home approved protocols will be reviewed by the UACC Subcommittee for approval. See the UACC Policy on Animal Based Projects Involving Two or More Institutions.

   b) New Animal Use Protocols (AUPs) should be submitted to the UACC Coordinator at least two months in advance of the anticipated start date of the project or course. Because the UACC can request clarification of any missing or incorrect information, submitting an incomplete application can add a month or more to the approval process. Please be advised that research funding cannot be released until all applicable approvals are in place (including scientific merit when applicable).

1.2) In order to achieve the objective of ensuring that the use of vertebrate animals at Queen's University meets or exceeds the standards of animal welfare established by the Animals for Research Act (Ontario), and the Canadian Council on Animal Care, the UACC reviews all Queen’s University sanctioned activities involving live animals whether they are to occur on Queen’s property or otherwise. In order to facilitate this process, the UACC requires advance notice of any proposed events. Although a full animal use protocol may not be required, general information will need to be provided for review and final approval by the UACC Subcommittee prior to any activities taking place. See the UACC Policy on Activities Involving Live Animals.

1.4) Investigators must submit and be approved for any modification to a current protocol prior to implementing any changes by completing a protocol amendment. Amendments will be classified as administrative, minor or major. See the UACC Policy on Protocol Amendments for full definitions and procedures.

1.5) Renewals are to be submitted within the one-year approval period. Renewal submissions must describe all new changes to the protocol since the previous approval; provide an update on previous approval period outcomes as they relate to complications, adequacy of humane interventions and study endpoints, and a description of the use and distribution of animals as compared to that which was previously approved. A justification for the number of animals being requested must be provided regardless of any changes.

1.6) Full Resubmission protocols must include an update on the previous approval period outcomes as they relate to complications, adequacy of humane/study endpoints, and a description of the use and distribution of animals as compared to that which was approved will be required.

1.7) A protocol closure report collecting information on why the study is no longer being pursued is required upon completion of a protocol (or when a PI chooses not to renew or to abandon a protocol). An update on outcomes as they relate to complications, adequacy of humane/study endpoints, and a description of the use and distribution of animals as compared to that which was approved will be sought and PI’s will be encouraged to explain if/ how the research objectives were reached and to indicate any publications or additional research opportunities that arose out of the research.

1.8) All protocol submissions (new, renewal and amendment) must be submitted in Topaz Elements. Investigators are encouraged to consult the UACC Coordinator, the UACC Chair or the University Veterinarian with any questions they may have before submitting a protocol for review.
2. Procedures of the Animal Care Committee

2.1) The UACC shall meet monthly. Additional meetings may be held at the call of the Chair.

2.2) The UACC shall require that all animal use at Queen’s University for teaching, testing, or research by University personnel or University affiliated research members, complete and submit to the UACC an animal use protocol (AUP), which will be maintained within the Topaz Elements database. All Queen's University sanctioned activities involving live animals, whether they are to occur on Queen’s property or otherwise also need UACC approval prior to taking place.

2.3) Protocols are reviewed prior to the scheduled UACC meeting and discussed by all members at the meeting where all final decisions are reached by consensus.

2.4) The UACC has the authority to assess all animal facilities at any time, and shall do so at least once a year to evaluate facilities and provide a visual of the areas where animals are housed ensuring that all important criteria are being met; clarifying that the equipment and human resources are appropriate and sufficient; and helping to place the use of the facility into context. In person assessments are organized and conducted in conjunction with the facility manager and/or delegated staff. Shared and dedicated technical spaces within facilities will also be assessed. The UACC will coordinate with lab personnel to ensure that at least one representative user of the space is present as it is critical to communicate directly with the individuals who conduct work in these spaces. All members of the UACC are encouraged to participate in at least one facility assessment on an annual basis.

Following every assessment, a formal report is generated for UACC review and distribution to the facility manager and all relevant staff/users. When follow up is required, a deadline will be provided and the UACC Coordinator will track responses and update the UACC accordingly. The University Veterinarian and UACC Chair will be included on all correspondence where concerns are noted. Senior administration responsible for animal care and use at Queen’s University (Vice Principal, Research) will be provided with all reports. Senior administration will be contacted for additional support if significant breaches of compliance develop. See the UACC Policy on the Oversight of Animals in Science.

2.5) The UACC shall conduct annual laboratory assessments of all areas outside of the facilities where animals are used. Assessments are conducted to review compliance with the CCAC Guidelines, Animals for Research Act and UACC policies, to better understand the in vivo work being done, to meet with those performing the in vivo work, and to encourage open communication between researchers and the UACC. In person laboratory assessments will be conducted in teams consisting of at least one UACC member, the UACC Coordinator and when feasible the University Veterinarian. Assessments will be arranged according to location; therefore, laboratories close in proximity will be toured the same day. As it is a critical component of the assessment to communicate directly with the individuals who conduct work in these spaces, the UACC will provide the date and time of the tour in advance to encourage that animal users (technicians, students, researchers etc.) can arrange to be present. PI’s and laboratory personnel will be consulted during the scheduling process. If no individuals who conduct animal work are available, the assessment will be rescheduled.

The UACC Coordinator will provide each team with a guide and will record all findings as well as concerns or recommendations raised by research personnel. Summary memorandums to individual PI’s and present lab personnel will be generated by the UACC Coordinator for electronic distribution. The University Veterinarian and UACC Chair will be included on all correspondence where deficiencies affecting compliance are noted. When follow up is required, PI’s will be provided with a deadline and the UACC Coordinator will track responses accordingly, updating the UACC as needed.

Senior administration will be provided with a summary of all laboratory assessment findings and all summary memorandums will be made readily available. Senior administration will be contacted for additional support if significant breaches of compliance develop. See the UACC Policy on the Oversight of Animals in Science.

2.6) The UACC shall establish procedures for post approval monitoring of animal use protocols and define the roles and responsibilities of the members of the animal care and use program in the monitoring process.

To facilitate compliance as dictated by the Animals for Research Act (ARA), Canadian Council on Animal Care (CCAC) guidelines and policies, and institutional policies and standard operating procedures (SOPs), a Quality Assurance Program (QAP) has been implemented. This program provides support to the research community while ensuring the protection of animal subjects by confirming accurate and consistent UACC approved protocol
2.6a) QAP assessments are managed by the QAP Coordinator who 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) provides training for non-compliant activities.

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 Review

• The QAP Coordinator will give advance notice of announced visits to the PI via email outlining which protocol is undergoing review. The PI 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. 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 if there are concerns regarding any observations. Once the report has been reviewed by both parties, a final version will be sent to the PI 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 distribution, however all QAP reviews will be presented to the UACC at the following meeting.

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

The QAP Coordinator in conjunction with the UACC is responsible for determining and working to correct breaches of compliance with approved animal use protocols and SOP’s. The QAP Coordinator will work with the concerned animal users, the UACC, Veterinarian, animal care staff and the senior administration to correct all breaches of compliance. All members of the animal care and use program will be informed about sanctions that will be taken by the administration in the event of serious breaches of compliance.

Where there are persistent breaches of compliance or threats to the health and safety of personnel or animals, these will be reported back to the UACC. The UACC will promptly address these issues through communications with the animal user(s), meetings and site visits, and communications with senior administration as necessary.

2.7) The UACC delegates the Veterinarian(s) the authority to treat, remove from a study or euthanize, if necessary, an animal according to the Veterinarian’s professional judgement. The Veterinarian will attempt to contact the animal user before beginning any treatment that has not previously been agreed upon, but the Veterinarian has the authority to proceed with any necessary emergency measures, whether or not the animal user is available. A written report will be sent by the Veterinarian to the animal user and to the UACC following any such event. The Veterinarian and UACC may also choose to delegate certain responsibilities to one or more senior animal care staff member(s).

2.8) The UACC will maintain an active dialog with senior administration through communications with the UACC Chair and the University Veterinarian. Senior administration will be sent a summary document quantifying all annual activities of the UACC (protocol reviews, facility assessments, laboratory assessments etc.) and all UACC meeting minutes and assessment reports will be made readily available. Senior administration will be updated on any ongoing issues and issues of non-compliance as well as for general support on relevant matters.

2.9) The UACC will communicate frequently with the animal care and use community as a whole with respect to general matters (explanations of the role of the ACC and of practical animal care and use matters including information for protocol submission UACC meeting schedules, policies, standard operating procedures (SOPs), training opportunities, etc.), and with animal users, veterinary and animal care staff, hazardous substances committees, occupational health and safety groups/officials and others as often as needed to ensure that the program is functioning appropriately. UACC bulletins will be circulated to ensure adequate and consistent distribution of information. The Animals in Science website will host policies, SOPs and all bulletin content.

3.1) Investigators shall submit all Animal Use Protocols (AUPs) to the UACC Coordinator using the electronic protocol management system Topaz Elements. Once submitted, all protocol submissions including renewals and amendments undergo review to detect preliminary concerns. New submission protocols and full resubmission protocols may also undergo a veterinary preliminary review. Comments and/or questions, resulting from the preliminary reviews are corresponded to the PI. This feedback should be incorporated into a resubmission of the protocol. If there are no suggested revisions, the submission will be assigned to UACC review accordingly. Incomplete applications or those received past the deadline may be deferred to the next monthly meeting.

3.2) The UACC Coordinator shall assign a primary and secondary reviewer to each new submission protocol (level B-E); full resubmission protocol (level B-E) and level E protocol renewal. These reviewers will be responsible for reviewing and leading the discussion of the protocol at the next regularly scheduled UACC meeting. All remaining members of the UACC (apart from those where a conflict of interest is present) will be assigned the protocol as committee reviewers, granting them access to view and comment on the protocol without a requirement to do so.

3.3) Level A new and full resubmission protocols are reviewed and approved by the UACC Subcommittee, consisting of the Chair, the Veterinarian and a community member. Level A renewals are reviewed and approved by the UACC Coordinator. The CCAC does not require that an animal use protocol be maintained for level A work, however the UACC has found it beneficial to maintain records for level A protocols where invertebrates are housed in animal facilities on campus. Researchers unsure of their need to submit an animal use protocol should contact the UACC Coordinator.

3.4) Level B-D protocol renewals are reviewed by the UACC Subcommittee, consisting of the Chair, the Veterinarian and a community member. The UACC reviews for approval, all actions of the Subcommittee by way of the Subcommittee Reviews Report which is submitted to each monthly meeting. This report includes renewals, pilot progress reports, protocol closures, inter-institutional collaborations, protocol revisions and amendments. To ensure transparency, the report provides a comment summary as sent to the PI (regardless of the review outcome). The Subcommittee reserves the right to defer any renewal submission to the UACC should the proposed changes warrant further review.

Renewals are to be submitted before the protocol is due for renewal (within the one-year period). Monthly reminders are circulated for at least 3 months prior to the renewal date. Renewal submissions must describe all new changes to the protocol since the previous approval as well as provide a progress report on the outcome of the last approval period. This includes complications encountered relative to animal health and welfare and how they were resolved as well as the adequacy of the humane interventions and study endpoints and a description of the use and distribution of animals as compared to that which was previously approved. A justification for the number of animals being requested must be provided regardless of any changes. To facilitate continuity, renewals should be submitted at least 2 weeks before their renewal date.

3.5) After UACC members have completed their reviews, they shall discuss the proposal at a full UACC meeting and, taking account of the members’ evaluations, either a approve (with or without comments), b return for modification (for subsequent review by the UACC Subcommittee), or c decline the proposal, requiring it be revised and resubmitted to the next full UACC meeting for subsequent review.

If the members of the UACC reviewing the proposal so indicate, they shall be given an opportunity to see any clarifications/revisions that may be provided by the PI. Reviewers shall also have access to the PI’s grant application(s) and/or other appropriate documents in order to satisfy themselves concerning the nature of the experimental procedures to be utilized. The UACC Coordinator may contact the PI to collect further information on behalf of any reviewer.

3.6) Once a protocol has been approved, the PI will receive a notification stating so. If the protocol has not been approved the PI will receive notification explaining the conditions upon which the protocol will/may gain approval status. The office of the UACC maintains the Topaz Elements database of current and historical protocols. UACC members, facility managers (and delegated staff), animal care staff, and University Research Services (URS) staff will have ‘view only’ access to all current and historical protocols as needed.

3.7) A one-year approval period is granted with the possibility for three consecutive yearly renewals (4 years total). Prior to the expiry of the one-year approval period, the PI is sent at least three reminder emails stating that the project will require renewal should the PI wish to continue the research. A full resubmission protocol is required after the full 4-year approval period. Allowing active protocols to expire, when animals work is continuing is considered a breach of
compliance. When renewals are approved past the renewal date, the one-year approval period will be pre-dated to fall in line with the initial period and when renewals are approved prior to the renewal date, the one-year approval period begins the date of approval. Approval periods can be no greater than 1 year and the life of any one protocol cannot exceed 4 years total. Short term renewal date extensions may be requested only under special circumstances provided the subsequent renewal or full resubmission has been submitted.

3.8) During the course of the project, protocol changes may be requested by an amendment. There are three categories of amendments:

a. Administrative amendments are straightforward changes to the protocol which do not affect animal use or welfare. They are to be reviewed and approved by the UACC Coordinator (with consultation of the UACC Chair and University Veterinarian as required). Administrative amendments are usually assessed within 2-3 days of submission.

b. Minor amendments are changes to the protocol which may affect animal use or welfare, but do not increase the category of invasiveness. At the discretion of the UACC Chair and the University Veterinarian, or delegates, modifications may be referred to the full UACC for review, which will add further time to the review process. Minor amendments are usually assessed within 4-5 days of submission.

c. Major amendments are changes which affect animal use or welfare, including but not limited to those increasing the original category of invasiveness. The UACC meets once per month, therefore major amendments can only be processed on a monthly basis. Substantial modifications may result in a request to submit a completely new Animal Use Protocol.

See the UACC Policy on Protocol Amendments for examples of changes constituting administrative, minor and major amendments.

The UACC reserves the right to determine whether a change is too significant to approve as an amendment and must be submitted as a new protocol. All protocol amendments are reported to the full UACC for comment at the monthly meeting in the Subcommittee Reviews Report.

3.9) To justify animal use, the UACC must be satisfied that a project has scientific merit. Research protocols must indicate whether the project has been peer-reviewed for scientific merit. Where the applicant confirms that an independent peer-review has not been undertaken, arrangements for arm’s length peer-review must be made and the review successfully completed before the protocol is approved. A reviewer pool will be maintained by the UACC Coordinator with suitable reviewers from this pool being selected by staff within the Office of the Vice Principal (Research). The UACC Coordinator will approach the selected reviewers to provide written assessment of the proposed research. A scientific summary of the research protocol is sent for review, along with a reviewer comment form which includes a statement requesting declaration of the relationship between the reviewer and the PI to ensure an arm’s-length review. In addition, the reviewer must declare whether they are qualified to review the proposal. As a minimum, one reviewer must be external to the UACC. In addition, regardless of the funding source, peer-review for scientific merit may be sought for any protocol where, in the judgement of the UACC, the specifics of animal use have not been adequately justified or explained. Reviews are documented and must contain sufficient information to support reviewer conclusions.

4. Pilot Projects

The UACC encourages the use of pilot studies with few animals when new approaches, methods, or products are being tried. Animal users must report on the results of pilot studies, regardless of whether they wish to pursue the study immediately or not, in order to preserve important data on various approaches to animal-based studies, whether they work well or not.

Submitting a pilot project for review entails the same process as submitting a new protocol. When completing the protocol, it must be labelled as a pilot project. At time of renewal, regardless of whether the study is to continue, a pilot progress report must be completed. If the study is to continue, a full resubmission must be submitted. Pilot extensions of up to 1 year are available if nothing is changing within the application and little or no progress was made during the initial 1-year period.

5. Interim Approval
In the event that interim approval (approval prior to the next meeting of the UACC) is required, the PI should submit the protocol following the regular process however communicating approval needs to the UACC Coordinator including clear justification for this request. The UACC delegates the responsibility of interim approvals to the UACC Subcommittee. Interim approvals are subject to discussion and final approval at a full UACC meeting.

6. Appeal Mechanism

In the event the UACC rejects a submitted protocol for either ethical or scientific reasons and the PI does not accept the decision, the following process will apply:

6.1) The PI may request that the UACC reconsider its decision. This could include the submission of a revised protocol following feedback from the UACC via the Chair. Reconsideration may involve the PI meeting with the UACC so that they may thoroughly review and understand the details of the protocol. The UACC may seek scientific opinions from individuals who are not members of the UACC.

6.2) If this does not provide a satisfactory solution, then the PI may appeal to the Vice-Principal, Research (the Senior Administrator responsible for the animal care and use program). The VP (Research) will then work with both the UACC and the PI to endeavor to find a satisfactory solution.

7. Conflict of Interest

It is the responsibility of the institution and the UACC to ensure that the use of animals within the institution and by its members reflects the standards of the society within which that institution exists. Therefore, every effort will be made to have diversity on the UACC and to avoid conflicts of interest in order to keep decisions balanced and fair. This is true for each category of member on the UACC.

Conflict of interest is defined as a situation in which a person or organization is involved in multiple interests (financial, emotional, or otherwise), one of which could possibly corrupt the motivation of the individual or organization.

If at any point during the protocol review process a conflict of interest arises, the protocol reviewer is asked to declare the conflict to the UACC Coordinator and if necessary they can be removed from the assignment (reviewers who do not feel comfortable reviewing a protocol for any reason will be accommodated). If a conflict of interest becomes apparent during a UACC meeting, affected individuals are asked to declare the conflict. The UACC strives for transparency and all final decisions are reached by consensus.

8. Confidentiality

All UACC members must respect the confidentiality of UACC matters and the privacy of the proposed work and intellectual property that they are reviewing. The UACC, the institution and the individuals participating in animal-based science must work together to ensure that the UACC has all the information necessary to conduct an appropriate ethical review of the proposed projects, while ensuring that confidentiality is maintained. All UACC members will sign a confidentiality agreement annually. See the UACC Policy on Confidentiality.