TRINITY WESTERN UNIVERSITY

INSTITUTIONAL ANIMAL CARE COMMITTEE

Instructions for Completing Animal Use Protocol Application Forms

Trinity Western University (TWU) requires that all research or teaching projects involving the use of animals be covered by an Animal Use Protocol (AUP) approved by TWU's Institutional Animal Care Committee (IACC).

I. General Information

TWU's IACC requires that:

a. applicants use the standard forms created by the IACC. All forms below are available online at http://www.twu.ca/research/research/animal-care/protocols.html.
   - -for new applications, complete the applicable Animal Use Protocol Form:
     - -Application For Vertebrate Projects
     - -Application For Vertebrate Projects Involving Wildlife
     - -Application For Invertebrate Projects
   - -for annual renewals, complete the Annual Renewal Form.
   - -for changes (amendments) to your protocol, complete the relevant form:
     - -Amendment Form - for personnel changes
     - -Amendment Form - for procedural or Principal Investigator/Instructor changes

b. forms are typed
c. forms must be signed by the Principal Investigator/Instructor and his/her Dean.
d. every required section is completed (see section VI for assistance)
e. the project title matches the grant application/course title (include course #)
f. applications be renewed annually for ongoing projects with a new application being submitted every four years.
g. any changes to an approved protocol be approved by the IACC before implementation.
h. protocols must adhere to CCAC guidelines and policies and to TWU's IACC Terms of References.
i. no project begins, nor can animals be acquired, prior to approval by the IACC.
j. A signed hard copy and an electronic copy, with all supporting documentation (such as Standard Operating Procedures not already on file, permits, etc) are to be submitted to the IACC Coordinator, Darcy Kehler at kehler@twu.ca.

II. Deadlines for submitting protocols

For projects starting in:	September	January	May
Protocols must be submitted by:	June	October	February

III. Period of Validity

AUPs are valid for one year and may be renewed annually for up to three consecutive years. A new application form must be submitted after the fourth year.

IV. Renewals

For AUPs continuing beyond one year, complete the Annual Renewal Form each year and submit it to the IACC for review. The form is available at http://www.twu.ca/academics/research/animal-care.

V. Protocol Changes

Any change to the protocol requires completion of an Amendment Form. There are two forms, one for Personnel changes and one for Principal Investigator/Instructor or Procedural changes. Complete the form(s) that is/are applicable.
For major changes, a new protocol may be required. Examples of major changes may include a considerable increase in the number of animals required or the use of more invasive, more frequent or entirely new procedures.

VI. Explanatory Notes to Assist with Completion of the Animal Use Protocol Form

Period of Validity
Provide a proposed start and end date.
For long term projects, the maximum acceptable end date is four years (ie the maximum duration of a protocol before requiring a new protocol submission)

Submission Information
Indicate if this is a first submission, a revision of the first submission (as requested by the IACC) or a resubmission (ie 4 years after the first protocol submission)

Section 1: General Information

Course Number and Project Title
This must match the grant application title. If not, there may be a delay in releasing funds by the Research Office.

Principal Investigator/Instructor (PI)
Only a faculty member of TWU may submit a protocol application. Students are to be listed as associates. The Application Form must be **signed by the PI and his/her Dean.**
The PI is the person with overall responsibility for the project and to ensure the guidelines and policies of the CCAC and TWU are adhered to, such as properly caring for animals used and that personnel involved have the relevant training and experience.
The Dean ensures that TWU has the necessary facilities that meet the CCAC guidelines.

Section 2: Protocol Description

Protocol Summary
Provide a brief description of the protocol using lay terminology. Details should be sufficient to ensure that all members of the IACC understand what will happen to the animals and can assess

the merit and humaneness of the procedures. Keep the terminology simple and the description under 250 words. Not all members of the IACC may be familiar with the scientific terminology of your field and this summary may be used for press releases and public presentations.

Keyword Descriptions
Keywords provide a succinct description of the project. This is required for the Animal Use Data Form submitted to the CCAC annually by the IACC.
Below is a list of suggested keywords by the CCAC. Additional keywords may be used.

General	• research, teaching, testing, regulatory (if the experiments are performed directly in relation to testing regulations in force in Canada and/or the US (FDA, EPA, etc.) and/or elsewhere), type of testing (e.g., cosmetic testing), field work, behavioral observation, environmental protection study, wildlife conservation, development of techniques, study of the effectiveness of a product (drugs, others) or a method (spectroscopy, others), breeding, breeding colony, sentinel program, antibody production (monoclonal, polyclonal), pilot study, palatability test, digestibility test, reinforcement/motivation, staged behavioral encounters, primary cell culture, tissue/organ collection, graft, transplant, species, transgenic animal, validation of non-animal model (*in vitro* test, computational methods...)
Procedures	•trapping/netting, marking/tagging, injection (intravenous, subcutaneous, intramuscular, intraperitoneal), blood sampling/testing (small volume), blood removal (large volume), gavaging, physical restraint (duration), infection induction, whole-body radiation, implantation, food deprivation, water deprivation, special diet, altered environmental exposure, euthanasia (chemical, physical), anesthesia
Agents	Radioisotope administration, chemical exposure, infectious agents, immunogenic or inflammatory agents, Freund's complete adjuvant, antibiotics, analgesics
Surgery	major surgery, minor surgery, stereotaxic surgery, survival surgery, multiple surgeries, cannulation

Section 3: CCAC Categorizations

Purpose of Animal Use (PAU)
Refer to the CCAC document below and check the box that is most appropriate to the project.

PAU 0	**Breeding Colony/Stock** Animals held in breeding colonies (e.g., fish, rodents) that have not been assigned to a particular research, teaching or testing protocol.
PAU 1	Studies of a **fundamental nature** in sciences relating to essential structure or function (e.g.: biology, psychology, biochemistry, pharmacology, physiology) **Possible examples:** studies designed to understand the cellular and/or molecular basis of inflammatory reactions or other basic physiological or biochemical reactions; studies designed to understand one or some of the various facets of the role played by a hormone or other compound produced by mammals; studies designed to better understand the behavior of various species; studies designed to better understand the population dynamics of various species
PAU 2	Studies for **medical purposes**, including veterinary medicine, that relate to human or animal diseases or disorders. These are studies carried out to better understand a specific disease or disorder and to help find therapies for it.

	Possible examples: development of a mouse model for a specific type of cancer or other disease; studies to determine which antibodies are the most likely to contribute positively to the therapy of a specific type of cancer; studies to determine which molecule within a particular class of compounds is the most likely to contribute to maintaining stable blood glucose levels in an animal model of diabetes
PAU 3	Studies for **regulatory testing** of products for the protection of humans, animals, or the environment. **Possible examples:** safety testing, regulatory toxicology, vaccine efficacy trials and testing of new therapeutic compounds (if it is to generate data that is going to be used in a submission for an Investigational New Drug Application (IND) or for a New Drug Submission (NSD); shellfish toxin.
PAU 4	Studies for the **development of products or appliances** for human or veterinary medicine These are the studies carried out to investigate potential therapies (as determined following studies of PAU 2) for humans or animals, before regulatory testing (PAU 3) is carried out on the most promising therapies. **Possible examples:** studies undertaken in animals to investigate the role and effects of a specific drug or immunotherapy candidate for cancer; studies undertaken to develop physical devices to assist heart function; studies undertaken to develop artificial organs.
PAU 5	**Education and training** of individuals in post-secondary institutions or facilities. These are teaching or training programs where animals are used to introduce students to scientific work and teach manual skills and techniques.

Category of Invasiveness (COI)
Refer to the CCAC document below and categorize the protocol according to the **most** invasive procedure being carried out.
Complete the “Application for Projects Using Vertebrates” or the “Application For Vertebrate Projects Involving Wildlife” for COIs B, C, D, or E.
Complete the “Application for Projects Using Invertebrates” for COI A.

CCAC’s Categories of Invasiveness (COI) in Animal Experiments (1991)

Investigators and teachers who consider it essential to use vertebrates or invertebrates in their research, teaching or testing in the laboratory or in the field, must adhere to humane principles, and take cognizance of the Canadian Council on Animal Care's (CCAC) Ethics of Animal Investigation *and other CCAC documentation in assigning a category. Protocols must be submitted to an appropriate review committee for all studies and courses which involve the use of vertebrates and some invertebrates in Categories B through E. Cephalopods and some other higher invertebrates have nervous systems as well developed as in some vertebrates, and may therefore warrant inclusion in Category B, C, D, or E.*

The following list of categories provides possible examples of experimental procedures which are considered to be representative of each category:

A. **Experiments on most invertebrates or on live isolates**

Possible examples: the use of tissue culture and tissues obtained at necropsy or from the slaughterhouse; the use of eggs, protozoa or other single-celled organisms; experiments involving containment, incision or other invasive procedures on metazoa.

B. **Experiments which cause little or no discomfort or stress**

Possible examples: domestic flocks or herds being maintained in simulated or actual commercial production management systems; the short-term and skilful restraint of animals for purposes of observation or physical examination; blood sampling; injection of material in amounts that will not cause adverse reactions by the following routes: intravenous, subcutaneous, intramuscular, intraperitoneal, or oral, but not intrathoracic or intracardiac (Category C); acute non-survival studies in which the animals are completely anesthetized and do not regain consciousness; approved methods of euthanasia following rapid unconsciousness, such as anesthetic overdose, or decapitation preceded by sedation or light anesthesia; short periods of food and/or water deprivation equivalent to periods of abstinence in nature.

C. **Experiments which cause minor stress or pain of short duration**

Possible examples: cannulation or catheterization of blood vessels or body cavities under anesthesia; minor surgical procedures under anesthesia, such as biopsies, laparoscopy; short periods of restraint beyond that for simple observation or examination, but consistent with minimal distress; short periods of food and/or water deprivation which exceed periods of abstinence in nature; behavioral experiments on conscious animals that involve short-term, stressful restraint; exposure to non-lethal levels of drugs or chemicals. Such procedures should not cause significant changes in the animal's appearance, in physiological parameters such as respiratory or cardiac rate, or fecal or urinary output, or in social responses.

Note*: During or after Category C studies, animals must not show self-mutilation, anorexia, dehydration, hyperactivity, increased recumbency or dormancy, increased vocalization, aggressive-defensive behavior or demonstrate social withdrawal and self-isolation.*

D. **Experiments which cause moderate to severe distress or discomfort**

Possible examples: major surgical procedures conducted under general anesthesia, with subsequent recovery; prolonged (several hours or more) periods of physical restraint; induction of behavioral stresses such as maternal deprivation, aggression, predator-prey interactions; procedures which cause severe, persistent or irreversible disruption of sensorimotor organization; the use of Freund's Complete Adjuvant .

Other examples include induction of anatomical and physiological abnormalities that will result in pain or distress; the exposure of an animal to noxious stimuli from which escape is impossible; the production of radiation sickness; exposure to drugs or chemicals at levels that impair physiological systems.

Note*: Procedures used in Category D studies should not cause prolonged or severe clinical distress as may be exhibited by a wide range of clinical signs, such as marked abnormalities in behavioral patterns or attitudes, the absence of grooming, dehydration, abnormal vocalization, prolonged anorexia, circulatory collapse, extreme lethargy or disinclination to move, and clinical signs of severe or advanced local or systemic infection, etc.*

E. **Procedures which cause severe pain near, at, or above the pain tolerance threshold of unanesthetized conscious animals**

This Category of Invasiveness is not necessarily confined to surgical procedures, but may include exposure to noxious stimuli or agents whose effects are unknown; exposure to drugs or chemicals at levels that (may) markedly impair physiological systems and which cause death, severe pain, or extreme distress; completely new biomedical experiments which have a high degree of invasiveness; behavioral studies about which

the effects of the degree of distress are not known; use of muscle relaxants or paralytic drugs without anesthetics; burn or trauma infliction on unanesthetized animals; a euthanasia method not approved by the CCAC; any procedures (e.g., the injection of noxious agents or the induction of severe stress or shock) that will result in pain which approaches the pain tolerance threshold and cannot be relieved by analgesia (e.g., when toxicity testing and experimentally-induced infectious disease studies have death as the endpoint).

Classification – Acute vs Chronic

Acute studies are generally those where the animals are utilized for a brief period (eg less than 24 hours) or are housed without any manipulations carried out until they are briefly needed experimentally. Eg: nonrecovery surgery, euthanasia followed by tissue collection.

Chronic studies are those where animals are housed and experimental procedures are carried out on the animals during this time. Eg: recovery surgery, breeding colony, antibody production

Section 4: Personnel

Associates
All personnel who will handle animals, along with their training and qualifications with respect to animal handling must be listed. Include contact information.
In the case of undergraduate students, who may have very little training, close supervision is required.

Emergency Personnel
In case of emergency, list at least two associates from section 4a who can be contacted.

Additional Assistance Personnel
List any personnel who may be required to provide additional animal expertise to ensure the project is carried out competently and humanely.

Section 5: Animal Use

Use
List all animals that are to be used.
If both invertebrates and vertebrates are being used in the same experiment/course, list both under the vertebrate AUP.

Housing/Location
List how and where animals are to be housed to ensure space and handling requirements are appropriate. Specify the environmental enrichment (EE) provisions to be used as a means to refine animal care, i.e. social housing, specific materials, space, objects, etc.
Refer to the CCAC's 'Social & Behavioural Requirements of Experimental Animals'.(Appendix 2), or the CCAC Guide to the Care & Use of Experimental Animals Vol. - 2nd Edition p.51-74.
Any limitations on EE from that normally offered to housed animals, based on CCAC guidelines, must be justified to the IACC.
For field studies, include any ecological impacts that may take place.

By-Catch Species

For field/wildlife studies, include precautions taken to avoid capturing non targeted (by-catch) species as well as actions taken if captured.

Regulatory Requirements
Include copies of all required licenses/permits.

Section 6: Animal Use Justification and Alternatives

The use of animals in research, teaching, and testing is acceptable ONLY if it promises to contribute to understanding of fundamental biological principles, or to the development of knowledge that can reasonably be expected to benefit humans, animals or the environment.

Animals should be used only if the researcher's best efforts to find an alternative have failed. A continuing sharing of knowledge, review of the literature, and adherence to the Russell-Burch "3R" tenet of "Replacement, Reduction and Refinement" are also requisites.
Those using animals should employ the most humane methods on the smallest number of appropriate animals required to obtain valid information.
For further information, read the CCAC policy statement, “Ethics of Animal Investigation” available online at: http://www.ccac.ca/en_/standards/policies/policy-ethics_animal_investigation .

Justify animal usage on **scientific or statistical grounds** with regard to the Three Rs (replacement, reduction and refinement) of animal use.

- Explain why a particular species/strain was chosen. Cost may not be used as a justification.
- Explain how the proposed animal numbers were derived to emphasize that the smallest number of animals are being used while still fulfilling statistical validity. The explanation should give an indication of the experimental design, group sizes, and statistical analyses to be used. Stating “the number requested is necessary for statistical analysis” is not sufficient.
- Provide the numbers required over the course of **one** year only. Further animal numbers can be approved in yearly protocol renewals.
- Explain why animals must be used and justify why replacement alternatives cannot be used (such as non-animal methods, cell/tissue culture, computer simulations, audio-visual teaching methods, replacement of sentient animals with animals of lower sentiency, etc).
- Include any alternatives that are already incorporated into the protocol.
- List databases on alternatives searched. A useful reference is the CCAC Three Rs Search Guide at http://searchguide.ccac.ca/.
- Describe refinements that have been made to minimize pain, distress and/or discomfort to the animals or which protect and enhance animal health and welfare.
  Possible examples: improved anesthesia and analgesic methods, modified procedures, shortened period that animals are used/held, refined housing and husbandry methods, medical treatment as appropriate under veterinary care.

Section 7: Procedures

List all procedures to be carried out on animals to provide a procedural summary to the IACC. To ensure animals will be properly handled and used, the level of training of individuals performing the procedures, or who will be responsible for their training, needs to be indicated.

Give a **clear, sequentially detailed description of all procedures, manipulations and techniques** to be used on animals in this protocol that matches the order of the procedures list requested. The use of graphic representations is encouraged.
Use terminology understandable to all ACC members, including non-scientists.

Refer to approved Standard Operating Procedures (SOPs) whenever possible to help keep the AUP succinct. This is especially useful for projects with multiple and/or routine procedures (eg blood sampling or injections. The IACC should receive a copy of all SOPs and these will be regularly reviewed by the IACC.

Include any other information considered important or necessary and pertinent, including information or results derived from any relevant previous protocols. The description and use of previous relevant results is particularly important to ensure that methodologies are not simply re-used without learning from any animal welfare problems that were encountered in the past, that the protocol continues to have relevant goals and methodology, and that appropriate refinements to protect and enhance animal welfare are sought and implemented.

Capture, Restraint and Transportation
When protocols involve wild animals, their lack of conditioning results in high levels of stress when captured and handled. It is important to provide detailed descriptions regarding all pursuit, capture, handling, restraint (method and duration), transportation, housing and technical procedures to be carried out with explanations of their appropriateness. Criteria used to assess frequency of observation and suitability for release must be clearly stated. Provision for recovery, treatment or euthanasia of potentially injured animals and disposal of carcasses must be specified. Include precautions taken to protect both the animals and people involved.

Animal Identification and Tracking
Provide details of any animal identification/tracking methods used, including how it is applied, any potential side effects, and how the equipment will be retrieved, if applicable.

Section 8: Drugs and Chemical Use

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All drugs or chemicals used on animals must be listed in order to assess efficacy, appropriateness and potential safety concerns. There is considerable variability between species regarding drug dosages and possible drug contraindications/interactions so it is important to include the agent name, the dosage, route of administration, frequency/duration of action, species receiving the agents, person administering and expected/potential side effects.

Anesthesia is to be conducted by, or under the knowledge or supervision of qualified staff. Analgesics (pain relievers) are routinely given if there is any concern that an animal may experience pain/distress as a result of a procedure. Strong scientific justification must be provided if not using anesthesia or analgesia in the case of invasive protocols.

It is recommended that a veterinarian be consulted for the appropriate use of drugs and chemicals.

Section 9: Monitoring, Endpoints and Fate of Animals

Monitoring
Specify the frequency for monitoring animals and include any relevant checklists of symptoms to be used when evaluating the animals. As a minimum, a normal animal should be examined at least once per 24 hour period as part of a routine health check.

Endpoints

All protocols, even non-invasive ones, must have clearly identified "endpoints" to ensure that any animals requiring treatment are treated and that animals are not simply kept indefinitely.

The term "endpoints" is defined by the CCAC as the point at which an experimental animal's pain and/or distress is terminated, minimized or reduced, by taking actions such as euthanizing (killing) the animal humanely, terminating a painful procedure, or giving treatment to relieve pain and/or distress. See the CCAC guidelines on: choosing an appropriate endpoint in experiments using animals for research, teaching and testing, 1998. **Death is not an acceptable endpoint.**

Information for identifying and applying endpoints must be readily available, and preferably posted, in the area where the animal-based work is taking place.

Fate of Animals
Specify the fate of the animals used, such as released, euthanized, relocated, adopted, etc)
For animals being euthanized, describe the method used. The technique chosen should induce unconsciousness rapidly with death following soon after; typically, a chemical method, such as an overdose of an anesthetic drug or gas is used. If a physical method of euthanasia is to be used (eg because the use of drugs could jeopardize the results of the study), justify its use.
If approved by the IACC, competence will need to be demonstrated in the presence of a qualified animal care committee member or designate. The name of the person euthanizing needs to be included to ensure they are competent to do the procedure humanely.

See the CCAC website for the most recent guidelines on acceptable euthanasia methods, www.ccac.ca, or contact the IACC Veterinarian.

Section 10: Hazards

If hazardous materials are to be used, TWU's Occupational Health and Safety Committee must approve their use. This section is to alert people of potential dangers and to ensure that appropriate precautions are being taken to protect people, animals and the environment.

Section 11: Additional Information

Appendix A: Brief Summary of Pedagogical Merit
Complete for teaching projects to better capture information regarding teaching programs and to indicate that the pedagogical merit of using live animals has been demonstrated.

Appendix B: Brief Summary of Scientific Merit
Complete for research projects. Provide a brief summary of the objectives and the potential value of the study.
Indicate whether the project has received peer review for scientific merit.
If a review has not been carried out by an external, peer review agency, the Institutional Animal Care Committee (IACC) will contact the protocol applicant as the IACC will require that it be obtained according to the CCAC guidelines on: animal use protocol review, 1997 and the CCAC Policy on the Importance of Independent Peer Review of the Scientific Merit of Animal-Based Research Projects, 2000.