

 **UNIVERSITI PUTRA MALAYSIA**

**INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)**

**Application for Ethics Approval for Research Projects Involving Animals**

1. Projects involving live animals must be approved by UPM IACUC prior to commencement of the animal study.
2. Please complete the application form in accordance to the UPM Guidelines. Application must be word-processed or typewritten. Incomplete application will be returned to the applicant, resulting in delay in the granting of approval.

3. Following endorsement by the Dean/Director/Deputy Dean/Deputy Director, submit one softcopy and three hardcopies of the following documents to the IACUC Secretariat:

i. Animal Utilisation Protocol (Form IACUC/101)

ii. Scientific merit review on the animal study

iii. Brief research proposal

iv. One or two pertinent research papers related to the proposed animal/disease model

v. Supporting documents (approval, grant offer letter, permit, etc.)

vi. Animal Utilisation Protocol Checklist and Review (Form IACUC/107)

4. Direct all applications and enquiries to:

The Secretariat

Institutional Animal Care and Use Committee

c/o Unit of Ethics Research

Level 4, Office of the Deputy Vice Chancellor (Research & Innovation)

Universiti Putra Malaysia

Attention to: Ms. Nor Ellia Abd Ajis

Email: n\_ellia@upm.edu.my/ iacuc@upm.edu.my

Phone: 03-8947 1244/ 1605

**GENERAL INFORMATION**

* The principal investigator is responsible to ensure that all facets of animal care and use meet the requirements of the **UPM POLICY AND CODE OF PRACTICE FOR THE CARE AND USE OF ANIMAL FOR SCIENTIFIC PURPOSES**.
* The Code of Practice embodies the principles of the 3R’s which are:
* Reduction of animal use
* Replacement of animal use
* Refinement of animal use

It is important to consider these principles when designing and carrying out studies.

* The transportation, care and use of animals should be in accordance with the Animal Welfare Act 2015, Wildlife Conservation Act 2010 and other applicable federal laws and state enactment, guideline and policies.
* Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.
* The animal selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation and *in vitro* biological systems should be considered.
* Proper use of animals, including the avoidance or minimization of discomfort, distress and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.
* Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anaesthesia. Surgical or other painful procedures should not be performed on unanaesthetised animals paralyzed by chemical agents.
* Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or if appropriate, during the procedure. Death is not an endpoint unless justified.
* The living conditions of animals should be appropriate to their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care shall be provided as indicate.
* Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures in living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.
* The application should be presented in a way that explained in detail the care and use of animals from the beginning to the completion of a project. This would include factors that will have an impact on animals such as housing (type, duration, opportunity for social interaction) as well as all treatments (substances, dose rates, routes, volumes, anaesthetics, surgical procedures etc.) and the expected effects. Flow charts or sequence of event tables are often of assistance.
* The application should also explain and justify clearly the choice of animals, the species, the number of animals and the qualifications of personnel undertaking the study.

***Endorsed by:***

***Dean/Director/ Deputy Dean/***

***Deputy Director***

**Institutional ANIMAL CARE AND USE COMMITTEE**

**Universiti Putra Malaysia**

***Animal Utilisation Protocol - Research***

*This completed Animal Utilisation Protocol (AUP) needs to be submitted to,*

*and approved by UPM IACUC prior to commencement of the animal study.*

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| **PROJECT TITLE:****(*Related* *to the animal work only and must include the animal model to be used in the study*)**  |
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| --- | --- | --- | --- |
| **Starting Date:** |  | **Completion Date:** |  |

 dd/mm/yr dd/mm/yr

**1. PERSONNEL**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Institution/Department** | **Phone Number/e-mail** | **Signature** |
| **Principal Investigator:** |  |  |  |
| **ALL other personnel involved in the project:**  *Please indicate role (co-researcher, technical staff, RA, GRA)* |  |  |  |
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| **Attending veterinarian:***(Please also read and sign on Appendix 1)* |  |  |  |
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**2. RESEARCH PROJECT INFORMATION**:

**For RESEARCH, is this a pilot / preliminary study? [ ] YES [ ] NO**

**Has funding been approved for this study?**

 [ ] No, applying for funds

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| --- | --- |
| [ ] Yes – Provide Grant No: |  |

 \*Please attach a copy of approval letter(s).

**Peer Review for Scientific Merit of Research Studies has been performed by:**

|  |  |  |
| --- | --- | --- |
| [ ] Granting Agency  | [ ] Graduate Student Advisory Committee  | [ ] Other (*Specify*) :  |

Please provide a copy of reviewer’s comments.

**Purpose of Animal Use (check one):**

[ ] Studies of a fundamental nature in sciences relating to essential structure or function (i.e. biology, psychology, biochemistry, pharmacology, physiology, behaviour, etc.)

[ ] Studies for medical purposes, including veterinary medicine, that relate to human or animal disease or disorders.

[ ] Studies for regulatory testing of products, for the protection of humans, animals, or the environment.

[ ] Studies for the development of products or appliances for human or veterinary medicine, animal nutrition, animal reproduction and/or animal care.

[ ] Education and training of individuals in post-secondary institutions or facilities

[ ] General operating protocols (for routine management of herds/colonies)

[ ] Diagnostic testing.

**Classification (check one):**

[ ] ***Acute*** - utilising an animal for a brief period (less than 24 hrs.), followed by euthanasia or return of the animal to source, **or** humanely killing an animal upon receipt or after a brief housing period during which time no manipulations other than standard management procedures are performed, i.e. anaesthetized without recovery, euthanised for tissue collection, etc.

[ ] ***Chronic*** - maintaining the animal and performing experimental procedures during this time, i.e. feeding trials, antibody production, breeding colony, recovery surgery.

**Category of Invasiveness (check one):**

|  |  |
| --- | --- |
|  **A** | Involve either no living materials or use of no living materials, or use of plants, bacteria, protozoa, - studies on tissues obtained from autopsy or slaughterhouse. THIS CATEGORY DOES NOT NEED AN AUP |
| **[ ] B** | Experiments on vertebrates species, expected to produce little or no discomfort- mere restraint for blood sampling, injection of harmless substance, physical examination, - experiment on completely anaesthetised animals which do not regain consciousness, food/water deprivation for few hours, standard methods of euthanasia (anaesthetic overdose or sedation/light anaesthesia follow by decapitation) |
| **[ ] C**  | Experiments that involve some minor pain/discomfort for short duration to vertebrate species-exposure of blood vessels, implant chronic catheters, behavioural study involving short-term stressful restraint, immunization employing Freund’s adjuvant, surgery under anaesthesia resulting in minor post-surgical discomfort |
| **[ ] D** | Experiments that involve significant but unavoidable stress or pain to vertebrate species-deliberate induction of behavioural stress, major surgical procedure resulting in significant post-operative discomfort, induction of anatomical/physiological deficit resulting in pain/distress, application of noxious stimuli from which escape is impossible, prolonged (> several hours) physical restraint, procedures that produce pain in which anaesthetics are not used (toxicity testing with death as end-point, production of radiation sickness, certain injections, stress and shock research resulting in pain approaching pain tolerance threshold/point of intense reaction) |
| **[ ] E** | Procedures that involve inflicting severe pain near, at, or above the pain tolerance threshold of unanaesthetised, conscious animals-use of paralytic agent alone for surgical restraint without use of anaesthetics, severe burn or trauma infliction on unanaesthetised animals, inescapable severe stress or terminal stress  |

**3. LAY SUMMARY (250 words maximum)**

**In LAY TERMINOLOGY, please provide concise summaries of the following information. Avoid use of technical jargon. This summary may be used to justify this study.**

| **a) Research or instructional background and objectives.**  |
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| Background:Objectives:1.2.3. |

| **b) Anticipated impact and potential benefits to human and/or animal welfare.**  |
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**4. ANIMAL MODEL**

| **Justify the species and/or strain used for this research purpose. Please provide references for the proposed animal model or disease/condition** *(e.g. diabetes mellitus, osteoarthritis)****.*** |
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**5. ALTERNATIVES**

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| **a) Explain the necessity of using animals in this project, and why alternatives (*in-vitro and ex-vivo* systems) to replace the use of animals would be inappropriate to meet your project or teaching objectives. Please provide references.**  |
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| **b) Indicate any alternatives to animal use that are already incorporated into the project design *(in-vitro & ex-vivo* systems).** |
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**6. ANIMAL USE**

 **a) List all animals involved in the study**.

| **Quantity** | **Species/Strain** | **Weight/Age** | **Gender** | **Accommodation** **Building**  | **Experimental Room\*** [Eg: surgery or procedure room/area, or hatchery/pond/tank (for aquatic animals)] |
| --- | --- | --- | --- | --- | --- |
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|  |  |  |  |  | If you need more space for animals involved, please insert new rows |

\*Please specify if experiments on infectious diseases can be carried out in the proposed area/room. Please note that experiments involving infectious diseases that can be a threat to healthy animals cannot be permitted in the same facility.

| **b) Explain how the total number of animals to be used was determined.** e.g. 6 animals x 3 treatments = 18 animals. Include a flow chart or table if necessary.  |
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| **c) Indicate consideration given to reduce the use of animals in the project design.** |
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**7. SOURCE**

**Indicate the source or supplier:**

[ ] UPM Animal Resource Unit [ ] Client owned [ ] Client Donated [ ] UVH Resident Animal

[ ] Wildlife / field studies\* [ ] UPM Herd / Flock\* [ ] Local suppliers/farms\*)

[ ] Other institution(s)\* [ ] Import\*(attach health certificate & import permit)

[ ] Transfer from other researcher/ research\* (AUP No:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

 \* For the above, please provide details:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SPECIES** | **SOURCE/SUPPLIER** | **ADDRESS/LOCATION** | **PHONE NUMBER** | **MODE AND CONDITION OF TRANSPORTATION** |
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|  | If you need more space for animals involved, please insert new rows |  |  |  |

**8. ANIMAL CARE & HUSBANDRY**

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| 1. **Specify provisions of basic requirements for each species/strain of animals used**

**(For guide on species care and husbandry requirements, please refer to the UPM Code of Practice for the Care and Use of Animals for Scientific Purposes at http://www.rmc.upm.edu.my/dokumen/PTPPY1\_92272\_upm\_code\_of\_practice.pdf).** |
| **Species/strain 1**:\_\_\_\_\_\_\_\_\_\_\_\_\_i. Caging: [ ] Plastic [ ] Metal [ ] Aquarium [ ] Tank [ ] Others-specify\_\_\_\_\_\_\_\_\_\_\_\_\_ For aquaculture research, please specify size & volume of space : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ii. Stocking density: \_\_\_\_\_\_\_animal per \_\_\_\_\_\_\_\_\_\_\_\_\_(cage/pen/paddock/tank dimension or floor space) iii. Flooring/Bedding:[ ] Wood slatted [ ] Wire mesh [ ] Wood shaving [ ] Newspaper  [ ] Others\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_iv. Temperature of room: [ ] Not regulated [ ] Regulated at \_\_\_\_\_\_\_v. Ventilation: [ ] Not regulated [ ] Regulatedvi. Feed: [ ] Custom-formulated [ ] Commercial – name of manufacturer\_\_\_\_\_\_\_\_\_\_\_\_\_\_vii. Water: Source\_\_\_\_\_\_\_\_\_\_\_\_\_ Delivery: [ ] Bottle [ ] Water bowl  [ ] Others\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Species/strain 2**:\_\_\_\_\_\_\_\_\_\_\_\_\_(please copy items above ) |

 **b) Specify the frequency of the following activities (if applicable) and who will be performing**

|  |  |  |
| --- | --- | --- |
| **Activity** | **Frequency** | **Performed by (name)** |
| Feeding |  |  |
| Changing water bottle/bowl/tank |  |  |
| Changing bedding/litter tray/filter |  |  |
| Changing/cleaning cage/pen/tank/filter |  |  |

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| **c) Specify any enrichment provisions, i.e. specific materials** *(e.g. tissue paper)***, space, objects** *(e.g. cardboard shelter, cardboard tube)* **if any.**  |
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**9. PROCEDURES**

| **a)** **Using a FLOW DIAGRAM, describe how the animals will be used (sequence of research/teaching procedures that the animal will undergo) in this project. THE COMPLETE FLOW DIAGRAM MUST BE CLEAR AND SHOULD ONLY DESCRIBE THE PROCEDURES FROM THE POINT OF PURCHASE OR PROCUREMENT TO WHEN THE ANIMALS ARE EUTHANISED. In cases of surgical procedures, description of the following should be included; patient preparation before surgery, pain and distress management, frequency of monitoring during and post-surgery as well as technical description of surgical procedures. Please provide references where appropriate.** |
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|  |

**b) List ALL procedures, manipulations, and/or measurements that will be performed on the animals. Indicate what measures will be taken to alleviate or minimise any pain, distress or discomfort. Include post-operative care, specify analgesics & anaesthetics with dosages and routes of administration, and special procedures used.**

| **PROCEDURES**Including physical restraint, blood sampling, behavioural test, injection of compounds, e.g. anaesthetics, analgesics, antibiotics, chemicals, etc.  | **Frequency** (if same procedure is repeated in the same individual ) | **No. of animals involved**  | **(B-E)\***State of invasive-ness | **Compound name, dosage, route & volume**(if applicable) |
| --- | --- | --- | --- | --- |
| 1 |  |  |  |  |  |
| 2 |  |  |  |  |  |
| 3 |  |  |  |  |  |
|  | If you need more space for animals involved, please insert new rows |  |  |  |  |

\*Indicate the Category of Invasiveness for each procedure listed.

Please consult your AV for procedures involved the usage of drug (dosage, route, volume etc.).

**c) List ALL individuals who will carry out the procedures listed in 9 b).**

 **Provide their technical qualifications and relevant experience in performing these procedures**.

|  |  |  |
| --- | --- | --- |
| **Name** | **Procedure(s) to be** p**erformed** (list the corresponding procedure number as listed in table 9b above e.g. 1, 2, 3) | **Qualifications/experience with these procedures** |
|  |  |  |
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|  |  | If you need more space, please insert new rows |

Procedure involved the usage of controlled drug should be done by AV.

| **d) Specify the criteria used to assess the level of anaesthesia required for invasive procedures**  **(if relevant)**  |
| --- |
| [ ] Not applicable [ ] Respiratory rate [ ] Heart rate [ ] Corneal reflex [ ] Toe pinch [ ] Tail pinch [ ] Response to procedures [ ] Others – specify: |
| **e) Specify the methods/criteria for monitoring the condition/level of pain and distress of the animals following the above listed procedures.** **(Please attach Template of Animal Assessment/Monitoring Sheet)** |
| [ ] Not applicable [ ] Loss of appetite [ ] Loss of weight [ ] Restlessness [ ] Laboured breathing [ ] Loss/reduce mobility [ ] Abnormal resting posture [ ] Unresponsiveness[ ] Failure to show natural inquisitiveness [ ] Failure to groom/unkempt appearance [ ] Red stains around eyes of rats [ ] Guarding/protecting painful area[ ] Licking, biting, scratching, shaking of affected area [ ] Others – specify: |
| **f) Specify frequency of animal observations:**1. Daily husbandry routine: \_\_\_\_\_\_times per hour / day / week \**(delete where not relevant)*2. Following experimental procedures: \_\_\_\_\_\_times per hour / day / week \**(deletel where not relevant)* |

**10. EXPERIMENTAL AND/OR ANIMAL USE ENDPOINT**

When experimental procedures produce animals that may become ill, it is necessary to define an endpoint to ensure that an experimental animal’s discomfort, pain and/or distress is terminated, minimised or reduced.

| **a) Indicate any clinical conditions or abnormalities *expected or that could arise* as a result of the proposed study or teaching exercise** *(e.g. behavioural changes such as increased grooming, vocalization or postural changes, or physical abnormalities such as anorexia, dehydration, diarrhoea, etc.)* |
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|  |
| **b) In terms of species-specific behavioural changes and physiological signs, list the criteria that will be used to trigger the decision to remove an animal from the experiment, or to terminate the experiment** *(e.g. moribound, 20% body weight loss for a week, etc.)*. **If death is required as the endpoint, please justify.** |
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**11. DISPOSAL OF ANIMALS**

|  |  |  |
| --- | --- | --- |
| **SPECIES,** **quantity** | **TO BE RETAINED/ SOLD TO/ DONATED TO/ TRANSFERRED TO/ ADOPTED BY *(****specify location or to/by whom)* | **TO BE EUTHANISED** *(specify method/drug/dose. If a physical method of euthanasia is to be used i.e. cervical dislocation, justify its use)***CARCASS DISPOSAL** (*specify method)* |
|  |  |  |
|  |  |  |

1. **EMERGENCY VETERINARY CARE**

Is routine veterinary care appropriate for animals in this project? **[ ] YES [ ] NO**

If NO, attach specific instructions in case an emergency should arise.

*In the event of an animal health emergency, if the personnel LISTED IN SECTION 1 COULD NOT BE CONTACTED, the decision of a Clinical Veterinarian APPOINTED BY THE IACUC will be final.*

**13. HAZARDS:**

**Does this project involve hazardous agent or animal? [ ] YES [ ] NO**

 **If YES, please specify the details as below.**

|  |  |
| --- | --- |
| **TYPE:** | **SPECIFY AGENT, DOSAGE, ROUTE, FREQUENCY** |
| Radio-Isotope |  |
| Carcinogen |  |
| Dangerous chemical |  |
| Contagious pathogen to humans [ ] animals [ ] |  |
| \*Recombinant DNA/RNA |  |
| Other (e.g. \*GMO, electroshock) |  |
| **Special animal care or containment procedure required because of the hazard(s) involved is/are:** |

**\*Project involving Recombinant DNA/RNA/GMO needs to apply for acknowledgement (contain used) or approval (field trial) from National Biosafety Board or UPM Institutional Biosafety Committee (IBC).**

**14. INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE APPROVAL**

Upon approval, a protocol number will be assigned. This number must be used when ordering animals. This Animal Utilisation Protocol is valid for the duration of the project pending on submission of annual progress report by the investigator and recommendation by the animal facility manager.

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| **PRINCIPAL INVESTIGATOR’S DECLARATION** |
| By signing this form, I certify that:1. this project will be conducted in accordance with the Animal Welfare Act 2015 under Section 26 (<https://www.aaalac.org/resources/Malaysia.pdf>), UPM policy and Code of Practice for the Care and Use of Animals for Scientific Purposes ([http://www.rmc.upm.edu.my/dokumen/ PTPPY1\_92272\_upm\_code\_of\_practice.pdf](http://www.rmc.upm.edu.my/dokumen/%20PTPPY1_92272_upm_code_of_practice.pdf)) and Institutional Care and Use Committee (IACUC) guidelines, and any other applicable federal/state laws and regulations.
2. the information provided in this AUP is complete and accurate.
3. the proposed experimental activities described above have not been carried out by myself or other researchers in this institution or elsewhere.
4. all activities are designed to assure that pain/distress/discomfort of animals is minimized.
5. all personnel listed in section 9c are aware of, and will follow the approved procedures outlined in this form. They will be appropriately trained and qualified, and that I am responsible for the supervision, training, and work of said personnel.
6. I will maintain appropriate animal records (e.g. animal monitoring sheet, veterinary care, euthanasia, surgery, anesthesia etc.).
7. veterinary care will be available when necessary, and provided by the qualified attending veterinarian (AV). I will immediately notify his/her regarding any unexpected study results that negatively impact the animals, and any unanticipated pain or distress, morbidity or mortality will be documented and reported to the IACUC.
8. the information provided in this AUP will be kept current and any changes must be notified by submitting Form IACUC/105. I aware that IACUC approval must be obtained prior to performing the revised animal procedures described therein.
9. I understand that approval of proposed project is valid for a maximum of one (1) year from the date of approval. I aware that extension of the approval need to be requested at least one (1) month prior to project completion by submitting Form IACUC/106.
10. I will notify and submit Form IACUC/106 following the completion of project. I understand that my new AUP application will not be processed before report submission.
11. I understand that the IACUC may approve the application as submitted, required modifications in order to receive approval, or rejected, and the approval may be subject to further review.

**By submitting this form, I have read and understood the above declaration**. |
| Project Title:  |
| Signature and stamp of Principal Investigator:  | Date: |

**Appendix 1**

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| **ATTENDING VETERINARIAN’S DECLARATION** |
| By signing this form, I certify that:1. I should provide input in protocol review, the development of study removal criteria, and responsible conduct of research activities and can be invited to attend the IACUC meeting together with the research team if required.
2. I oversee the well-being and clinical care of animals used in research, testing and teaching. The responsibility extends to monitoring and promoting animal well-being at all times during animal use and during all phases of the animal’s life. Well-being is determined by considering physical, physiological and behavioural indicators.
3. I shall provide guidance to investigators and all personnel involved in the care and use of animals to ensure appropriate husbandry, handling, medical treatment, immobilization, sedation, analgesia, anaesthesia and euthanasia.
4. I shall provide guidance and oversight to surgery and perioperative care involving animals in accordance with current established veterinary medical and nursing procedures, if applicable.
5. I am expected to carry out daily observation of all animals in the study project to assess their health and well-being. However, the daily observation of animals may be accomplished by someone else other than myself provided that there is a mechanism of direct and frequent communication between the researchers and I so that timely and accurate information on problems of animal health, behaviour, and well-being is conveyed to me.
6. if I am on leave or will be otherwise unavailable to provide any general or emergency veterinary care, interim arrangements are made to ensure that there is always ready access to veterinary care. Timely provision of veterinary medical care and emergency veterinary care is always available after working hours, on weekends, and on holidays.
7. any unethical events or animals are not kept to optimum welfare care or found during an audit will be reported to the IACUC. I aware that the IACUC will initiate investigations where the researchers and I can be summoned for explanation and deliberation on the matter.
8. following the completion of project, I will notify the PI to submit a final report to the IACUC on the care and ethical use of animals in the project, including animal monitoring log if necessary.

**By submitting this form, I have read and understood the above declaration**. |
| Project Title: Name of Principal Investigator:  |
| Signature and stamp of Attending Veterinarian: | Annual Practicing Certificate number:  |
| Date: |