Impacts of the Animal Welfare Act 2015 on the use of animals in research

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## Preamble

- **Legislations governing the use of animals in (Peninsular) Malaysia**

<table>
<thead>
<tr>
<th>Animal (Amendment) Act 2013</th>
<th>Wildlife Conservation Act 2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal Welfare Act 2015</td>
<td></td>
</tr>
<tr>
<td>Ministry of Agriculture and Agro-based Industries (MOA)</td>
<td>Ministry of Natural Resources and Environment (NRE)</td>
</tr>
<tr>
<td><em>Fisheries Act 1985</em></td>
<td></td>
</tr>
<tr>
<td>-management, conservation, development of maritime and estuarine fisheries.</td>
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</tr>
<tr>
<td>-Species on the concurrent list of Federal Constitution may have state legislation as well.</td>
<td></td>
</tr>
</tbody>
</table>
Preamble

• Peninsular based IACUC should note that legislations governing the use of animals in Sabah and Sarawak are different.

• The Ninth Schedule Federal Constitution, detailing the distribution of power between Federal (List 1), State (List 2) and the Concurrent List (List 3 – protection of wild animals and birds, prevention of animal cruelty)

• Sabah and Sarawak had legislations that focused on the extraction, conservation and use of wildlife and (inland/riverine) fisheries in their respective states, for example the:
  • Wildlife Conservation Enactment 1997, Sabah;
  • Wildlife Protection Ordinance 1998, Sarawak;
  • Inland Fisheries and Aquaculture Enactment 2003, Sabah.
Preamble

• The Animal Welfare Act 2015 was gazetted on 29 December 2015.
• Implementation by stages, according to subsidiary legislations in stages. AWB is to be appointed (Jul 2017)
• Sections 24 and 29 enforceable since 1 June 2017 – Significant Impact on Animal Use in Research

Welfare vs Rights ?
Championing Animal rights ≠ Animal welfare

<table>
<thead>
<tr>
<th>OVERWHELMED BY EMOTION</th>
<th>GUIDED BY COMPASSION, FACTS &amp; DRIVEN BY EMOTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>The end justifies the means...extreme view is that animals must be totally liberated from human use</td>
<td>Compassion is an important impetus to improve animals’ well-being. Based on scientific evidence &amp; legislation. Cornerstone of “Animal Ethics”</td>
</tr>
<tr>
<td>Peter Sanger (1975)</td>
<td>Russell &amp; Burch (1959)</td>
</tr>
</tbody>
</table>
**Championing Animal rights ≠ Animal welfare**

<table>
<thead>
<tr>
<th>Championing Animal rights</th>
<th>Animal welfare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Using animals is NOT morally right</td>
<td>Using animals is morally justified as long as their welfare is taken care of</td>
</tr>
<tr>
<td>We should NOT use animals for our benefits</td>
<td>We should be allowed to use animals for our interest and benefits, e.g. foods &amp; medical cure etc.</td>
</tr>
<tr>
<td>We should not inflict pain, suffering and death on animals under all circumstances</td>
<td>We should avoid unnecessary pain, suffering and death on animals.</td>
</tr>
</tbody>
</table>
Why the misunderstanding?

• Differing views on whether animals have ‘rights’
• Legislation “vacuum” in most places and time until a century ago.
• Negative effects of humanisation
  ‘never humanize animals as animals are more than human’
• Portrayals of animal experimentations

Sad and Controversial
Harlow’s Monkeys Experiment

Food vs
Love & Affection

Pregnancy testing, circa 1940-50’s
The Five Freedoms

- Also known as Brambell’s Five Freedoms (5Fs) after Brambell’s Report 1965 commissioned by the UK’s government.
- Monitored through the Farm Animal Welfare Council
- Adopted by the OIE (World Organization for Animal Health) and the RSPCA.
- Gold standard … reflected in the veterinarian’s oath
- Defining principle that governs animal use guides from North America, Europe, East Asia, Oceania and the Malaysian Animal Welfare Act 2015 (Section 24).
### The Five Freedoms

<table>
<thead>
<tr>
<th>FREEDOM</th>
<th>INFLUENCING FACTORS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Freedom from hunger and thirst</td>
<td>By ready access to fresh water and a diet to maintain full health and vigour.</td>
</tr>
<tr>
<td>2. Freedom from discomfort</td>
<td>By providing an appropriate environment including shelter and a comfortable resting area.</td>
</tr>
<tr>
<td>3. Freedom from pain, injury or disease</td>
<td>By prevention or rapid diagnosis and treatment.</td>
</tr>
<tr>
<td>4. Freedom to express normal behaviour</td>
<td>By providing sufficient space, proper facilities and company of the animal’s own kind.</td>
</tr>
<tr>
<td>5. Freedom from fear and distress</td>
<td>By ensuring conditions and treatment that avoid mental suffering.</td>
</tr>
</tbody>
</table>
Animal Welfare

- OIE Definition (2008)

What is animal welfare?

In 2008 the OIE adopted a definition on animal welfare:

“Animal welfare means how an animal is coping with the conditions in which it lives. An animal is in a good state of welfare if (as indicated by scientific evidence) it is healthy, comfortable, well nourished, safe, able to express innate behaviour, and if it is not suffering from unpleasant states such as pain, fear and distress. Good animal welfare requires disease prevention and veterinary treatment, appropriate shelter, management, nutrition, humane handling and humane slaughter/killing. Animal welfare refers to the state of the animal; the treatment that an animal receives is covered by other terms such as animal care, animal husbandry and humane treatment.”

- Good animal welfare can be achieved through good practices associated with the 5F’s
- Foundation for laws and regulations e.g. the Animal Welfare Act 2015 / Malaysian Code of Practice for the Care and Use of Animals in Scientific Research
<table>
<thead>
<tr>
<th>Part</th>
<th>(Selected) Description &amp; Sections</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part I</td>
<td>Preliminary (Title &amp; Interpretation) (Sections 1-2)</td>
</tr>
<tr>
<td>Part II</td>
<td>Animal Welfare Board (Sections 3-14)</td>
</tr>
<tr>
<td>Part III</td>
<td>Licensing (Sections 15-23) &lt;br&gt; 13 activities in the schedule (Sec 15)</td>
</tr>
<tr>
<td>Part IV</td>
<td>Matters relating to animal welfare (Sections 24-28) &lt;br&gt; Duty of owner or licensee (Sec 24) THE FIVE FREEDOMS</td>
</tr>
<tr>
<td>Part V</td>
<td>Cruelty to animals (Sections 29-33) &lt;br&gt;Note the power and responsibilities of veterinary authority (and IACUC) in sections 30(1), 30(2) &amp; 30(3)</td>
</tr>
<tr>
<td>Part VI</td>
<td>Animals in distress (Sections 34-35) &lt;br&gt;Note the responsibilities of a registered veterinary surgeon and Animal Welfare officer in section 34</td>
</tr>
<tr>
<td>Part VII</td>
<td>Powers relating to enforcement (Sections 36-49) &lt;br&gt;Voluntary Animal Welfare Assistant in section 37</td>
</tr>
<tr>
<td>Part VIII</td>
<td>Ancillary powers of the court (Sections 50-55)</td>
</tr>
<tr>
<td>Part IX</td>
<td>General (Sections 56-64)</td>
</tr>
</tbody>
</table>
The AWA (as of 29 Dec 2015)

LAWS OF MALAYSIA
Act 772
ANIMAL WELFARE ACT 2015

ARRANGEMENT OF SECTIONS

PART I
PRELIMINARY

Section
1. Short title, application and commencement
2. Interpretation

PART II
ANIMAL WELFARE BOARD

3. Establishment of Animal Welfare Board
4. Functions of the Board
5. Delegation of functions of the Board
6. Membership of the Board
7. Alternate members
8. Tenure of office
9. Allowances and expenses
10. Resignation of appointment and resignation
11. Vacation of office
12. Meeting of the Board
13. Committees
14. Power of Minister to give directions

PART III
licensing

15. Requirement for licence
16. Application and issuance of licence
17. Licence not transferable
18. Duration of licence

PART IV
MATTERS RELATING TO ANIMAL WELFARE

24. Publication of owner or licensee
25. Improvement notices
26. Animals used in research, testing or teaching
27. Transport of animals
28. Selling of animals to persons under the age of twelve years old

PART V
CRUELTY TO ANIMALS

29. Cruelty offences
30. Killing of animals
31. Administration of poisons
32. Animal fighting venture
33. Failure to exercise reasonable care and supervision

PART VI
ANIMALS IN DISTRESS

34. Powers in relation to animals in distress
35. Orders in relation to animals taken into possession

PART VII
POWERS RELATING TO ENFORCEMENT

36. Animal welfare officer
37. Voluntary animal welfare assistant
Sections 26, 29-35 will be relevant to research institutions

Section 29 refers to the description of cruelty that falls under the purview of this act.

Sections, 41, 43, 44 stipulate the power to enter, seal premise and seize evidence and animals....
<table>
<thead>
<tr>
<th>Section 15(1)</th>
<th>Requirement for license for all activities</th>
</tr>
</thead>
</table>
| Section 16(1) - (4) | License application made to AWB, and AWB grants the license to an individual.  
- *Details described by Act Regulations for the use of animals in research, testing and teaching covering IACUC and Malaysian Code of Practice for the Care and Use of Animals for Scientific Purposes*  
- *IACUC will be a bridging body for review, records, monitoring and will assist should in the event of an investigation or legal query.*  
- *Mechanisms to bind individual researchers to existing research ecosystem in licensed institutions.* |
| Section 26(1) | Requirement for license for research, testing and teaching (RT&T) |
| Section 26(3) & (5) | License exemption for schools.  
- *Details described by a special guidelines for schools* |
| Section 26(4) | License requirement for breeding of animals for RT&T |
| Section 26(6) | Description of penalty (RM 20k – RM 100k) |
### Key Excerpts from AWA 2015

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 18</td>
<td>Duration of license (not more than 5 years)</td>
</tr>
<tr>
<td>Sections 19 &amp; 20</td>
<td>License renewal and display</td>
</tr>
<tr>
<td>Section 21</td>
<td>Suspension and revocation of licenses</td>
</tr>
<tr>
<td>Section 24</td>
<td>Duties of owner or licensee • <em>based on the 5 Freedoms</em> Section 24(3) further describe the penalty for violating the 5 freedoms</td>
</tr>
<tr>
<td>Section 27</td>
<td>Transportation of animals, restraint during transportation and penalties</td>
</tr>
<tr>
<td>Section 29(1)</td>
<td>Description of cruelty offences • <em>Note that any procedures that are not declared under IACUC can be persecuted under this section, e.g. inappropriate restraints, diet alteration or skin grafting etc. without approval</em></td>
</tr>
<tr>
<td>Section 29(2)</td>
<td>Exemptions from 29(1) by the Board-approved authorities, e.g. IACUC</td>
</tr>
</tbody>
</table>
Violations of 5Fs and AWA 2015

Seksyen 29
Perbuatan-perbuatan Penganiayaan Terhadap Haiwan

Menyepak, memukul, lebihkan muatan, mendera atau menakutkan haiwan
Terlebih naik atau tunggang (kecual bagi sukan ekuestrian)
Tidak memberi makan minum kepada haiwan yang dibela
Pengangkutan haiwan yang menyebabkan penderitaan kepada haiwan
Violations of 5Fs and AWA 2015

Seksyen 29
Perbuatan-perbuatan Penganiayaan Terhadap Haiwan

Menyimpan haiwan yang sakit tanpa alasan munasabah
Pertandingan menembak haiwan yang dilepaskan dari kurungan
Menyebabkan kesakitan, mencacatkan haiwan
Melapah atau membunuh haiwan kerana kepercayaan karut
Akta Kebajikan Haiwan 2015

Violations of 5Fs and AWA 2015

Seksyen 29
Perbuatan-perbuatan Penganiayaan Terhadap Haiwan

- Keluarkan bahagian haiwan yang masih hidup seperti untuk dapatkan kulit, minyak yang boleh menyebabkan kesakitan dan penderitaan pada haiwan
- Memasang dinamit
- Membiarkan haiwan yang berpenyakit keluar tanpa pengawasan
- Pelagaan haiwan (membantu, menyimpan, menguruskan, membenarkan, menerima wang)
Violations of 5Fs and AWA 2015

Seksyen 29
Perbuatan-perbuatan Penganiayaan Terhadap Haiwan

- Mengeletrikan atau membubuh racun ke dalam sungai bagi maksud membunuh haiwan.
- Membiarkan haiwan dirantai dengan tali pendek atau memincangkan kaki haiwan.
- Mengurung haiwan dalam sangkar kecil dan tiada pergerakan.
- Membuat tawaran jualan haiwan yang sakit.
Dan lain-lain seperti ….

Memperoleh dan memaksa haiwan yang sakit atau tidak berupaya untuk terus bekerja

Menggalak, menganjur, mengambil bahagian atau bersubahat dalam apa-apa cara dalam mana-mana aktiviti yang dinayatakan
### Key Excerpts from AWA 2015

<table>
<thead>
<tr>
<th>Section 30</th>
<th>Killing of animals (section 30(1)), circumstances where animals can be euthanized by a competent veterinary authority and/or IACUC (section 30(2)), REFERENCE TO IACUC (Section 30(3)), Section 30(4) Penalty. <strong>Researchers have to abide.</strong></th>
</tr>
</thead>
</table>
| Section 31(1) | Administration of poisons Requirement to obtain permission from AWB approved bodies, e.g. IACUC to treat animals with drugs and “poisons”. Poisons refer to any chemicals or compounds that could be detrimental to animals….  
• *Importance of IACUC Approval!* |
| Section 33(1) & 92 | Failure to exercise reasonable care and supervision (to animals)  
• *Importance of animal care description in IACUC form* |
| Section 34 | Powers in relation to animals in distress Authority of a registered veterinarian and AWO to order the destruction, relocation of distressed animals |
| Section 35 | Power in relation to animals taken into possession.  
• *Power of the courts* |
### Key Excerpts from AWA 2015

<table>
<thead>
<tr>
<th>Section 36</th>
<th>Appointment of Animal Welfare Officers – detailed by a specific Act Regulation.</th>
</tr>
</thead>
</table>
| Section 37 | Appointment of Voluntary Animal Welfare Assistants – detailed by a specific Act Regulation.  
  - AN IMPORTANT CHANGE: NGO’s & MEMBERS OF THE PUBLIC CAN BE APPOINTED! However, they do not have Investigation powers as appropriated by Section 39 |
| Section 40 | Search and seizure without warrant |
| Section 41 | Power to enter premises |
| Section 23 | Barred from holding license (not more than 5 years) |
| Sections 51 & 52 | Describe the legal provisions disqualifying an individual from having ownership and storage animals: Ancillary power of the courts for second offenders |
| Section 56 | Offences by organizations and body corporate.  
  - Home organization of the IACUC  
  - Needs for a structured and continuous training and inspection |
<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 62 (2)(c), (d), (j)</td>
<td>Power of the Minister to make new regulations after consultation with the Board. Section 62(2)(c) mentioned specifically on the need of laws to regulate animals used in RT&amp;T. Section 62(2)(j) describe the determination of fees and charges under this act.</td>
</tr>
</tbody>
</table>
| Section 64 | Transitional provisions  
  • *Transitional period* |
| Schedule  | *List of activities involving animals where act regulations should address* |
KEY Contents:

1. **General principles for the care and use of animals in scientific research**
   - Justifications for animal Use
   - Application of 3R principles (Reduce, Refine, Replace)

2. **Responsibilities of the institution and Institutional Animal Use & Care Committee (IACUC)**
   - Establishment & Terms of Reference of the IACUC
   - Composition of the IACUC (Categories A,B,C & D memberships)
   - Proposal review, monitoring, project reporting
   - Handling non compliant projects

3. **Responsibilities of the investigator(s)**
   - Project planning, suitability of models, procedures, termination and disposal of animals

4. **Acquisition and care of animals in breeding and holding facilities**
   - Transportation, quarantine, husbandry and veterinary care
   - Special sub-section on non human primate care

5. **Veterinary Care**
   - Role and responsibilities of the attending veterinarian
AWA Impacts

Impacts to the Institution

1. The need for IACUC – its structure and line of authority, animal use policy and activities that support IACUC functions e.g. record keeping, inspection, appraisal of proposals, training and competency, veterinary care – conforming to the Act Regulations on Animal Use in Research Teaching and Testing for licensing purposes.

2. IACUC approval should take into consideration the prevailing laws and legislation, protection status for the use of specific animal species, especially unconventional species e.g. turtles, sea horses, and others.

3. Man power, finances and facility investment (?) to uplift animal care and use. IACUC forms may need revision to incorporate all elements required by AWA2015.
Impacts to the Institution

4. Maintain oversight over animal use in the institution at all times. **KEEPING A SICK ANIMAL WITHOUT CARE IS AN OFFENCE!**

5. Opportunities for more established institutions to support in terms of training, consultancy and IACUC functions – UPM IACUC can perhaps play a role here.

6. Revision of research categories that require IACUC approval. Eventually all activities (teaching using live animals, courses and trainings using live animals) would require IACUC approval.

7. Need for (or with access to) attending veterinarian & veterinary care by MVC (Malaysian Veterinary Council) registered veterinarians with valid practicing credentials.

8. Need for end of project report
AWA Impacts

Impacts to the researcher and research associates

1. The need for IACUC approval becomes a legal requirement.
2. Welfare and veterinary medical needs of animal subjects superseed that of the research goals, unless with the relevant approval – Sections 29, 30 & 31.
3. Maintain oversight over animal use in research at all times.
4. Principal investigators has personal responsibility for animals under their care, as declared in their respective projects.
5. Animal handling competencies becomes mandatory.
6. Need for attending veterinarian & veterinary care by MVC (Malaysian Veterinary Council)-registered veterinarians with valid practicing credentials.
AWA Impacts

Impacts to the Researcher and research associates

7. All personnel involved in the research must be declared, this is the responsibility of the P.I.

8. Responsibility to file end of project report – enabling the IACUC to compile annual reports to the AWB as part of the licensing requirement.

9. The IACUC and/or the attending veterinarian has final say on the continuation of the research project

10. Keeping a sick animal without proper care, selling/transferring sick animal, working sick animal are all chargeable offences.
What if ?...

petaasiapacific protest June 2010
Application for Ethics Approval for Research Projects Involving Animals

1. Please complete the application form in accordance to the UPM Guidelines. Incomplete application will be returned to the applicant resulting in delay in the granting of approval.

2. Please submit a copy of a brief research proposal and an experimental flow chart of the animal study. One or two (or more) pertinent research papers related to the proposed study must also be submitted.

3. Application must be word-processed or typewritten.

4. All applications are to be submitted to the Deputy Dean’s (Research and Post Graduate Studies) office of your respective Faculty for evaluation of the scientific merit of the study after which 6 hard copies and a soft copy of the proposal are then submitted to:

The Secretariat, Institutional Animal Care and Use Committee, c/o Research Management Centre, Office of the Deputy Vice Chancellor (Research and Innovation), Universiti Putra Malaysia, Phone: 03-8947 1244; Fax: 03-8947 1634 (Attention Ms Suzita Ramli)

All enquiries should be directed to the secretariat at the above mentioned address and/or contact numbers.
GENERAL INFORMATION

- The 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 Act 1953 (Revised 2006), 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 unanaesthetized 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 indicated.

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.
Page 1 – form IACUC/101 – Scientific Merit review is important BUT it is not part of the IACUC’s job!

The UPM AUP form (current version 17th April 2018)

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.

PROJECT TITLE:

(Related to the animal work only and must include the animal model to be used in the study)

Starting Date:  
Completion Date:

<table>
<thead>
<tr>
<th>Name</th>
<th>Institution/Department</th>
<th>Phone Number/e-mail</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ALL other personnel involved in the project: Please indicate role (co-researcher, technical staff, etc.)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Attending veterinarian:  (Please also read and sign on Appendix 1)</td>
<td></td>
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</tr>
</tbody>
</table>
Section 2 Research Project Information – form IACUC/101

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
[ ] Yes – Provide Grant No: ____________________________

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

Peer Review for Scientific Merit of Research Studies has been / will be performed by:
[ ] Granting Agency  [ ] graduate Student Advisory Committee  [ ] Other (Specify):

Please provide copy comment by reviewer(s)

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 colonie)""""s
[ ] Diagnostic testing

Classification
[ ] Acute - Utilizing 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.
Section 2 Research Project Information – form IACUC/101

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

<p>| | | | | |</p>
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<tr>
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<tbody>
<tr>
<td>A</td>
<td>Involve either no living materials or use of no living materials, or use of plants, bacteria, protozoa, invertebrates, studies on tissues obtained from autopsy, slaughterhouse, embryonated egg</td>
<td><strong>THIS CATEGORY DOES NOT NEED AN AUP</strong></td>
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<tr>
<td>B</td>
<td>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 anaesthetized 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)</td>
<td></td>
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</tr>
<tr>
<td>C</td>
<td>Experiments that involve some minor pain/discomfort for short duration to vertebrate species - exposure of blood vessels, implant chronic catheters, behavioral study involving short-term stressful restraint, immunization employing Freund's adjuvant, surgery under anaesthesia resulting in minor post-surgical discomfort</td>
<td></td>
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<tr>
<td>D</td>
<td>Experiments that involve significant but unavoidable stress or pain to vertebrate species - deliberate induction of behavioral 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 (&gt; 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)</td>
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<tr>
<td>E</td>
<td>Procedures that involve infliction of severe pain near, at, or above the pain tolerance threshold of unanaesthetized, conscious animals - use of paralytic agent alone for surgical restraint without use of anaesthetics, severe burn or trauma infliction on unanaesthetized animals, inescapable severe stress or terminal stress</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Section 3 Lay Summary – form IACUC/101 … how outsiders are suppose to look at the project…..critical review from Category D committee Member will be important!

3. LAY SUMMARY (250 words maximum)

In LAY TERMINOLOGY, please provide concise summaries of the following information. Avoid use of technical jargon.

a) Research or instructional background and objectives.

b) Anticipated impact and potential benefits to human and/or animal welfare.
Section 5 Alternatives – form IACUC/101

- Justify why no alternatives should be used for this experiment
- In vivo trials typically require prior in vitro proofs
- In selected cases, committee may even recommend pilot studies to verify procedures
Section 6 Animal Use – form IACUC/101
- Number used, treatment group allocation and sample size derivations
- There must be evident separation of species for accommodation!

<table>
<thead>
<tr>
<th>Qty</th>
<th>Species/Strain</th>
<th>Weight/Age</th>
<th>Gender</th>
<th>Accommodation</th>
<th>Experimental Area</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Building &amp; Room</td>
<td>Building &amp; Room</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(surgery or procedure rooms/area)</td>
</tr>
</tbody>
</table>

If you need more space for animals involved, please insert new rows.

b) Explain how the total number of animals to be used was determined:
e.g. 6 animals x 3 treatments x 2 replicates = 36 animals. Include a flow chart or table if necessary.

c) Indicate consideration given to reduce the use of animals in the project/course design.
Section 7 Source of Animals – form IACUC/101

- Researchers should be mindful of the source of their animals
- Subjects should be procured legally, particularly for samples from outside Peninsular Malaysia, even Sabah and Sarawak….and those using wildlife!
- Transportation of animals is important – as heat stress, (>2-5 %) dehydration can adversely affect blood parameters, kidney and liver functions

<table>
<thead>
<tr>
<th>SPECIES</th>
<th>SOURCE/SUPPLIER</th>
<th>ADDRESS/LOCATION</th>
<th>PHONE NUMBER</th>
<th>MODE OF TRANSPORTATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>UPM Animal Resource Unit</td>
<td>Client owned</td>
<td>Client Donated</td>
<td>UVH Resident Animal</td>
<td>Wildlife/field studies</td>
</tr>
</tbody>
</table>

* For the above, please provide details:

If you need more space for animals involved, please insert new rows
### Section 8 Animal Husbandry & Care – form IACUC/101

#### 8. ANIMAL CARE & HUSBANDRY

a) Specify provisions of basic requirements for each species/strain of animals used (For guide on species care and husbandry requirements, please visit: http://www.ccac.ca/en/CCAC_Programs/Guidelines_Policies/GUIDES/ENGLISH/toc_v1.htm)

<table>
<thead>
<tr>
<th>Species/strain 1:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>i. Caging:</td>
<td>[ ] Plastic  [ ] Metal  [ ] Others-specify</td>
</tr>
<tr>
<td>ii. Stocking density:</td>
<td>animal per (cage/pen/paddock dimension or floor space)</td>
</tr>
<tr>
<td>iii. Flooring/Bedding:</td>
<td>[ ] Wood slatted  [ ] Wire mesh  [ ] Wood shaving  [ ] Newspaper  [ ] Others</td>
</tr>
<tr>
<td>iv. Temperature of room:</td>
<td>[ ] Not regulated  [ ] Regulated at</td>
</tr>
<tr>
<td>v. Ventilation:</td>
<td>[ ] Not regulated  [ ] Regulated</td>
</tr>
<tr>
<td>vi. Feed:</td>
<td>[ ] Custom-formulated  [ ] Commercial – name of manufacturer</td>
</tr>
<tr>
<td>vii. Water:</td>
<td>Source  Delivery: [ ] Bottle  [ ] Water bowl  [ ] Others</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species/strain 2:</th>
<th></th>
</tr>
</thead>
</table>

(please copy items above)

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

<table>
<thead>
<tr>
<th>Activity</th>
<th>Frequency</th>
<th>Performed by (name)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feeding</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Changing bedding/litter tray</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Changing/cleaning cage/pen</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**c) Specify any enrichment provisions, i.e. social housing, specific materials, space, objects if any.**
Section 9 Procedures – form IACUC/101 – empowerment, responsibility & competency

The UPM AUP form (current version 17th April 2018)

### 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 FLOW DIAGRAM SHOULD ONLY DESCRIBE THE SEQUENCE OF USE OF ANIMALS 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.

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

<table>
<thead>
<tr>
<th>PROCEDURES</th>
<th>Frequency (if same procedure is repeated in the same individual)</th>
<th>No of animals involved</th>
<th>(B-E)* State invasiveness</th>
<th>Anaesthetics/analgesics</th>
<th>Antibiotics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Including physical or chemical restraint, blood sampling, injection of compounds, e.g. antibiotics, chemicals, etc.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
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<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If you need more space for animals involved, please insert new rows</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

c) List ALL the individuals who will carry out the above procedures. Provide their technical qualifications and relevant experience in performing these procedures.

<table>
<thead>
<tr>
<th>Name</th>
<th>Procedure(s) to be performed (list the corresponding no. 1, 2, etc.)</th>
<th>Qualifications / Experience with these procedures</th>
</tr>
</thead>
</table>
Section 9 Procedures – form IACUC/101

- Important to monitor food and water intake, as well as mobility of the animal
- Pain observation and monitoring that requires training and competency

The UPM AUP form (current version 17th April 2018)
Section 10 Experimental Animal Use Endpoint – form IACUC/101

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, minimized 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.)

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 teaching exercise or experiment, or to terminate the teaching exercise or experiment.

11. DISPOSAL OF ANIMALS

<table>
<thead>
<tr>
<th>SPECIES</th>
<th>RETAINED - specify location (if animals are not euthanized)</th>
<th>SOLD TO/ DONATED/ TRANSFERRED TO/ ADOPTED BY (specify)/ CARCASS DISPOSED (specify method)</th>
<th>EUTHANIZED specify method/drug/dose. If a physical method of euthanasia is to be used i.e. cervical dislocation, justify its use.</th>
</tr>
</thead>
</table>
Section 12 & 13 Emergency Veterinary Care & Hazards – form IACUC/101
- Responsibilities to the institution and community

12. EMERGENCY VETERINARY CARE

Is normal 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 CONTACT CANNOT BE MADE WITH THE PERSONNEL LISTED IN Q#1, THE DECISION OF A CLINICAL VETERINARIAN APPOINTED BY THE IACUC WILL BE FINAL.

13. HAZARDS:

<table>
<thead>
<tr>
<th>TYPE:</th>
<th>SPECIFY AGENT, DOSAGE, ROUTE, FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radio-Isotope</td>
<td></td>
</tr>
<tr>
<td>Carcinogen</td>
<td></td>
</tr>
<tr>
<td>Dangerous chemical</td>
<td></td>
</tr>
<tr>
<td>Contagious pathogen to humans [ ] animals [ ]</td>
<td></td>
</tr>
<tr>
<td>Recombinant DNA/RNA</td>
<td></td>
</tr>
<tr>
<td>Other (e.g. GMO, electroshock)</td>
<td></td>
</tr>
</tbody>
</table>

Specify what special animal care / containment procedure is required because of the hazard(s) involved:
Section 14 Declaration of the principal investigator – form IACUC/101

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 submission of annual progress report by the investigator and recommendation by the animal facility manager.

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.htm) UPM policy and Code of Practice for the Care and Use of Animals for Scientific Purposes (http://www.rmc.upm.edu.my/dokumen/PTPPY1%202272%20upm%20code%20of%20practice.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 him/her regarding any unexpected study results that negatively affect 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 acknowledge 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 understand that extension of the approval need be requested at least one (1) month prior to project completion by submitting Form IACUC/105.

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:
Appendix 1 Declaration of the attending veterinarian – form IACUC/101

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, 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 myself 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:
“…The greatest scientific experiments have always been the most humane and the most aesthetically attractive, conveying that sense of beauty and elegance which is the essence of science at its most successful…..“


The Principles of Humane Experimental Technique.
AKTA KEBAJIKAN HAIWAN 2015
[AKTA 772]
ADUAN
PENGABAIAN KEBAJIKAN HAIWAN &
PENGABAIAN HAIWAN

019-2242233  pro@dvs.gov.my  www.dvs.gov.my