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**UNIVERSITY OF MALAYA**

**FACULTY OF MEDICINE**

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

**Application for Approval of Animal Use Protocol (AUP)**

1. Please refer to the University of Malaya Faculty of Medicine IACUC Policy; <http://resfom.um.edu.my>
2. In order for the Faculty of Medicine Institutional Animal Care and Use Committee (FOM IACUC) to perform its obligations in accordance with the University Of Malaya Faculty Of Medicine IACUC Policy, it needs a complete description of the proposed animal use and care. Incomplete application will be returned to the applicant resulting in delay in the granting of approval.
3. Hand written documents will not be accepted for review.
4. Submission is to be made on the prescribed form electronically or by email, and accompanied by a signed hard copy **(6 hard copies)** to:

**The Secretariat, Faculty of Medicine Institutional Animal Care and Use Committee, c/o Research Management Centre (RMC), Level 3**

**Faculty of Medicine,**

**University of Malaya.**

**Phone: 03-7967 7515**

**Email:** [**fomiacuc@um.edu.my**](mailto:lindalahuddin@um.edu.my)(Attn to: Ms Haslinda Lahuddin)

All enquiries should be directed to the Secretariat at the above mentioned address and/or contact number.

1. Any changes to the approved Animal Use Protocol (AUP) (procedure, species, personnel, etc.) must be documented through submission of an Amendment Form and approved by the FOM IACUC before implementation.

**a)**Any **SIGNIFICANT** changes  to an approved project in progress (e.g. the inclusion of new procedures involving potential pain, surgery or anaesthetization, or a change in Principal Investigator or course director) require IACUC review (and approval) prior to initiation.

**b)**Any **NON-SIGNIFICANT** changes to an approved project in progress (e.g. increase in number of animals used within 10%, changes in location of experiment or changes in personnel) require administrative review (and approval) prior to initiation.

1. Approval of AUP will be for a **maximum of 3 years**. Following this, a new application is required.

**Office Use Only**

**Date received:**

**Application No.:**

**UNIVERSITY OF MALAYA,**

**FACULTY OF MEDICINE**

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

**Animal Use Protocol (AUP) Application**

*This completed Animal Use Protocol (AUP) Application needs to be submitted to and approved by the FOM IACUC prior to commencement of the animal study.*

**SECTION 1: APPLICANT INFORMATION**

**1a: Principle Investigator/Course Instructor**

*Principal Investigator here refers to the main person responsible for the care and use of animals in this protocol (i.e. not necessarily be the grant holder)*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Full name :** | | | | | | | | |
| **Designation** : | |  | Academic staff |  | Student | |  | Non-academic staff |
| **Department/Faculty :** | | | | | | | | |
| **Office no. :** | | | | | | **Mobile no. :** | | |
| **Email :** | | | | | | | | |
| **Experience or trained working with animals**? | | | | | | | | |
|  | **Yes** *Provide evidence which includes certificate of training, publication involving animal studies* | | | | | | | |
|  | **No** *Provide tentative date for training ( )* | | | | | | | |

**1b: Designated Emergency Contact(s) for animal related matters**

|  |  |  |
| --- | --- | --- |
| **Full Name** | **Mobile phone** | **Email** |
|  |  |  |
|  |  |  |

**1c: Co-Investigator(s)/Research Assistant(s)**

*List the names of all other individuals (besides the PI) authorised to conduct procedures involving animals under this protocol:*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Full name :** | | | | | | | | |
| **Designation** : | |  | Academic staff |  | Student | |  | Non-academic staff |
| **Department/Faculty :** | | | | | | | | |
| **Office no. :** | | | | | | **Mobile no. :** | | |
| **Email :** | | | | | | | | |
| **Experience or trained working with animals**? | | | | | | | | |
|  | **Yes** *Provide evidence which includes certificate of training, publication involving animal studies* | | | | | | | |
|  | **No** *Provide tentative date for training ( )* | | | | | | | |

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| **Full name :** | | | | | | | | |
| **Designation** : | |  | Academic staff |  | Student | |  | Non-academic staff |
| **Department/Faculty :** | | | | | | | | |
| **Office no. :** | | | | | | **Mobile no. :** | | |
| **Email :** | | | | | | | | |
| **Experience or trained working with animals**? | | | | | | | | |
|  | **Yes** *Provide evidence which includes certificate of training, publication involving animal studies* | | | | | | | |
|  | **No** *Provide tentative date for training ( )* | | | | | | | |

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| **Full name :** | | | | | | | | |
| **Designation** : | |  | Academic staff |  | Student | |  | Non-academic staff |
| **Department/Faculty :** | | | | | | | | |
| **Office no. :** | | | | | | **Mobile no. :** | | |
| **Email :** | | | | | | | | |
| **Experience or trained working with animals**? | | | | | | | | |
|  | **Yes** *Provide evidence which includes certificate of training, publication involving animal studies* | | | | | | | |
|  | **No** *Provide tentative date for training ( )* | | | | | | | |

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| **Full name :** | | | | | | | | |
| **Designation** : | |  | Academic staff |  | Student | |  | Non-academic staff |
| **Department/Faculty :** | | | | | | | | |
| **Office no. :** | | | | | | **Mobile no. :** | | |
| **Email :** | | | | | | | | |
| **Experience or trained working with animals**? | | | | | | | | |
|  | **Yes** *Provide evidence which includes certificate of training, publication involving animal studies* | | | | | | | |
|  | **No** *Provide tentative date for training ( )* | | | | | | | |

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| **Full name :** | | | | | | | | |
| **Designation** : | |  | Academic staff |  | Student | |  | Non-academic staff |
| **Department/Faculty :** | | | | | | | | |
| **Office no. :** | | | | | | **Mobile no. :** | | |
| **Email :** | | | | | | | | |
| **Experience or trained working with animals**? | | | | | | | | |
|  | **Yes** *Provide evidence which includes certificate of training, publication involving animal studies* | | | | | | | |
|  | **No** *Provide tentative date for training ( )* | | | | | | | |

**SECTION 2: PROJECT INFORMATION**

**2a:****Project Title**

*In lay terminology, please give a descriptive title of your research project or course taught*

|  |
| --- |
|  |

**2b: Type of project (☒all that apply):**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Research | ☐ | Others ☐ | Please specify: |  |
| Pilot study | ☐ |  |  | |
| Breeding protocol | ☐ |  |  | |
| Teaching | ☐ |  |  | |

**2c: Type of AUP application:**

|  |  |  |
| --- | --- | --- |
| ☐ | First submission |  |
| ☐ | Modification (IACUC approval no.) |  |

**2d: Proposed length of study using animals:**

|  |  |  |  |
| --- | --- | --- | --- |
| Start date: |  | End date: |  |

**2e: Project Funding**

|  |  |  |  |
| --- | --- | --- | --- |
| Grant type: | HIR/PPP/FRGS/Science Fund/Techno Fund/UMRG\* | | |
| Others: |  | |  |
| Funding status: | Awarded/Pending\* | Date awarded: |  |

*\* Please delete where appropriate*

**2f: Lay Summary**

Provide a typed abstract of **250 words** or less in simple language. Please include the overall objective, brief experimental approach, and significance of the expected results to human and/or animal health. State the readability score for **Flesch Reading Ease of the abstract (Target readability score: >50).** Please cite **three (3) recent references** related to the proposed study.

|  |
| --- |
| **Abstract:**  **(Flesch Score reading: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)**  <https://support.office.com/en-us/article/test-your-document-s-readability-85b4969e-e80a-4777-8dd3-f7fc3c8b3fd2#__toc342546557>  http://www.networkwithstyle.com/FKS.pdf  **References:** |

**2g:****Project Objective(s)**

|  |
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**SECTION 3: JUSTIFICATION OF ANIMAL USE AND THE THREE R’s**

*The FOM IACUC requires “that animals should be used only if the researcher’s best efforts to find an alternative have failed”. The three R’s (Replacement, Reduction and Refinement) are the cornerstone of ethical animal research, and FOM IACUC requires investigators to implement the 3R’s when they are preparing to use animals for scientific or teaching purposes.*

**3a:** 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 **three (3) relevant references**.

|  |
| --- |
|  |

**3b:** Why must animals be used in these experiments (☒all that apply)?

☐This is a study of animal behaviour

☐This phenomenon under study cannot be reproduced in vitro

☐This is a pre-clinical study of the in vivo effectiveness of a treatment or procedure

☐This is for teaching

☐Others (elaborate in the space below)

|  |
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|  |

**3c:** What characteristics of this/these species make them appropriate for the proposed study? These might include structural, behavioural, physiological, biochemical, or other features or considerations (such as availability of species-specific reagents, or the use of well-established model) which make the model compatible with the research objectives. **Cost is not a primary consideration**. Please provide **three (3) relevant references.**

|  |
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**3d:** If animals are housed for more than 24 hours in the animal facility, please select the appropriate housing and environmental enrichment conditions.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Species/Stock or strain 1 : | |  | | | | | | | | |
| Room temperature : |  | | 0C | to | |  | 0C | | | |
| Humidity: |  | | % | to | |  | % | | | |
| Caging : | ☐ Open cage | | | | ☐ IVC | | | ☐ Aquarium tank | | |
| Stoking density : |  | | | animal per | | |  | | (cage/tank) | |
| Bedding : | ☐ Corn cob | | | | ☐ Wood shaving | | | ☐ Others: | |  |
| Enrichment : | ☐ PVC tube | | | | ☐ Tissue paper | | | ☐ Others: | |  |
| Diet : | ☐ Normal diet | | | | ☐ Others: | |  | | |  |
| Water source : | ☐ RO water | | | | ☐ PVC tube | | | ☐ Others: | |  |
|  |  | | | |  | | |  | |  |
|  | | | | | | | | | | |
| Species/Stock or strain 2 (*please copy items above*) : | | | | | | | | | | |
|  | | | | | | | | | | |

**3e:** Will animals be singly housed at any point of time throughout the whole experiment?

|  |  |  |
| --- | --- | --- |
| **☐ Yes** | *If yes, please justify why and when*. | |
|  | Reason of single-house : |  |
|  |  |  |
|  | When to single-house: |  |
|  |  |  |
|  | Duration of sing-house: |  |
|  |  |  |
| **☐ No** |  |  |

**SECTION 4: EXPERIMENTAL DESIGN**

**4a: Experimental Design**

*Describe the experimental design; what will be done to the animals in a step-by-step description when applicable and include specific details such as administration route, dosage, frequency and sampling volume. Where possible, use charts and diagrams (may be added as appendices) to show relationships between different activities and demonstrate the distribution of animal numbers in different procedures. Please provide relevant references related to the experimental design.*

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**4b: Surgical Procedure**

Please tick the following:

☐ **Major survival surgery:** *any surgical procedure that penetrates and exposes a body cavity or produces substantial impairment of physical or physiological functions, or involves extensive tissue dissection or transection (Guide). Examples include but are not limited to: laparotomy, thoracotomy, ovariectomy, nephrectomy.*

☐ **Minor survival surgery:** *a surgical procedure that does not expose a body cavity and causes little or no physical impairment. Examples include: wound suturing, percutaneous biopsy, lymph node biopsy, laparoscopic oocyte collection, and subcutaneous osmotic mini-pump implantation.*

☐ **Multiple survival surgery:** *more than one survival surgery (major or minor) on a single animal*.

*If surgical procedure is involved, give details of the* ***procedure*** *and* ***pain management*** *before, during, and/or after surgical intervention in live animal studies. Please specify the anaesthetic, analgesic, antibiotic and other drugs used in pain management.*

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**4c: Procedures & Disease Progression**

*List* ***all*** *procedures manipulations, and/or measurements that will be performed on the animals, including disease progression in the animals. Specify post-operative care, analgesics & anaesthetics with dosages and routes of administration, and special procedures used. Information and examples on the classification can be obtained from these websites:*

* <https://www.research.va.gov/programs/animal_research/training/pain_distress_reference.doc>
* <https://research.ncsu.edu/sparcs/compliance/iacuc/iacuc-forms/pain-and-distress-categories/>
* <http://www.esf.edu/animalcare/documents/USDApainLevels.pdf>

| **Procedures**  Including physical or chemical restraint, blood sampling, injection of compounds, e.g. antibiotics, chemicals, etc. | | **Frequency**  (no. of times each animal is subjected to the same procedure) | **No. of animals involved** | **Pain/distress classification**  **(C, D, E)** | **Anaesthetics/**  **analgesics**  **Antibiotics** |
| --- | --- | --- | --- | --- | --- |
| Drug, dosage, route |
| 1 |  |  |  |  |  |
| 2 |  |  |  |  |  |
| 3 |  |  |  |  |  |
|  | If you need more space for animals involved, please insert new rows |  |  |  |  |

| **Disease Progression**  e.g. tumour progression, development of infection, development of disease condition | | **No. of animals involved** | | **Pain/distress classification**  **(C, D, E)** | **Anaesthetics/**  **analgesics**  **Antibiotics** |
| --- | --- | --- | --- | --- | --- |
| Drug, dosage, route |
| 1 |  | |  |  |  |
| 2 |  | |  |  |  |
| 3 |  | |  |  |  |
|  | If you need more space for animals involved, please insert new rows | |  |  |  |

**SECTION 5: CLASSIFICATION OF PAIN/DISTRESS**

*Please select the* ***overall*** *pain classification based on highest pain classification stated in Section 4c.*

|  |  |
| --- | --- |
| ☐C | **Classification C:** Animals upon which teaching, research, experiments, or tests will be conducted involving no pain, distress, or use of pain-relieving drugs. |
| ☐ D | **Classification D:** Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anaesthetic, analgesic, or tranquilizing drugs will be used. |
| ☐ E | **Classification E\*:** Animals upon which teaching, experiments, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which the use of appropriate anaesthetic, analgesic, or tranquilizing drugs will adversely affect the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. |

*\*An explanation of the procedures producing pain or distress in these animals and the justification for not using appropriate anaesthetic, analgesic or tranquilising drugs must be provided below.*

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**SECTION 6: ANIMAL USE**

**6a: List ALL ANIMALS involved in the study.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Species/Strain** | **Quantity** | **Weight/Age** | **Gender** | **Accommodation**  **(Building & Room)** | **Experimental Area (Building & Room -**  **surgery and/or procedure rooms)** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| *If you need more space for animals involved, please insert new rows* | | | | | |

**6b: Explain how the total number of animals to be used was determined:**

*e.g. 6 animals x 2 treatments x 2 replicates = 24 animals.*

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**SECTION 7: SOURCE OF ANIMALS**

*Please specify details of the animals in table below and indicate if health certificate (or equivalent) is available for the animals.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Species** | **Source/Supplier** | **Address/Location** | **Phone number** | **Health Certificate** | **Mode of transportation** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| *If you need more space for animals involved, please insert new rows* | | | | | |

**SECTION 8: EXPERIMENTAL AND/OR HUMANE 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.*

**8a:** 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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**8b:** *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. If necessary, consult the Attending Veterinarian for further advice at* [*azurawali@um.edu.my*](mailto:azurawali@um.edu.my)

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**SECTION 9: ANIMAL DISPOSAL**

*Indicate how animals are to be disposed of after completion of the project/research.*

Euthanasia [ select preferred technique(s)]:

|  |  |  |  |
| --- | --- | --- | --- |
| ☐ Anaesthetic overdose (specify agent(s): | |  | |
| ☐ CO2 | |  | |
| ☐ Cervical dislocation\* | |  | |
| ☐ Decapitation\* | |  | |
| ☐ Exsanguination (under anaesthesia) | |  | |
| ☐ Others (specify): |  | |

\* Provide justification for using physical methods of euthanasia, and state the location that it is done:

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Method of carcass disposal (Include method of disposing **contaminated organs/tissues**):

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**SECTION 10: HAZARDOUS AGENTS & MATERIALS**

Specify each agent/material to be used and hazardous dosage:

**NOTE: If a Biosafety and/or Radiation Safety risk assessment is required then a separate application must be submitted to the relevant bodies**.

|  |  |
| --- | --- |
| Potential Hazard to ***Animals*** ☐ None | |
| **Biological** |  |
| **Chemical** |  |
| **Carcinogen** |  |
| **Drug** |  |
| **Ionizing Radiation** |  |
| **Other (i.e. allergen)** |  |

|  |  |
| --- | --- |
| Potential Hazard to ***Humans*** ☐ None | |
| **Biological** |  |
| **Chemical** |  |
| **Carcinogen** |  |
| **Drug** |  |
| **Ionizing Radiation** |  |
| **Other (i.e. allergen)** |  |

Describe potential health risks to animals or humans. Specify any special animal care required because of the hazard(s) involved. Specify precautions to be taken by personnel. Specify any special containment requirements (i.e. storage, waste/disposal requirements, etc)

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**SECTION 11: SIGNATURES**

Your signature indicates that (check each box where applicable before signing):

|  |  |  |
| --- | --- | --- |
| 1 | ☐ | Animals used in this research or teaching project will be cared for in accordance with the principles contained in **Guide for the Care and Use of Laboratory Animal (8th Edition), until the Malaysia Code of Practice for the Care and Use of Animals for Scientific Purposes is made available.**  <http://oacu.od.nih.gov/regs/guide/guide.pdf> |
| 2 | ☐ | You have considered alternative procedures that do not involve the use of living animals. |
| 3 | ☐ | You will use the minimum number of animals consistent with objectives of described research/teaching program. |
| 4 | ☐ | You have carefully selected the species that you propose to use. |
| 5 | ☐ | You will use techniques and facilities that are in accordance with the **Guide for the Care and Use of Laboratory Animal (8th Edition)**  <http://oacu.od.nih.gov/regs/guide/guide.pdf> |
| 6 | ☐ | You will notify the FOM IACUC of any revisions to this AUP. |
| 7 | ☐ | You will keep copies of all approved AUPs, revisions and amendments in an accessible file. |
| 8 | ☐ | This project has been reviewed for scientific merit. |
| 9 | ☐ | Pharmaceutical grade chemicals are used, when available, for animal-related procedures. |
| 10 | ☐ | The consultant Attending Veterinarian has been contacted for consultation prior to AUP submission. AV signature : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 11 | ☐ | Experimental animals are housed in **Animal Experimental Unit**.  Animals from external sources need to be quarantined or housed according to the Standard of Procedure for Quarantine of Laboratory Rodent and Rabbit. |
| 12 | ☐ | Experimental animals are housed in other **Satellite Animal Facilities** in the Faculty of Medicine.  Animals from external sources need to be quarantined or housed according to the Standard of Procedure for Quarantine of Laboratory Rodent and Rabbit. |

Approval from the FOM IACUC is valid for a period of **three (3) years**. If required, AUP must be renewed after the expiry date even if no revisions are made. At the end of the animal experiment, **a closure report** of the animal use is to be submitted to FOM IACUC Secretariat at [fomiacuc@um.edu.my](mailto:fomiacuc@um.edu.my) .

|  |  |
| --- | --- |
| **AUP form completed by:** |  |
| **Email address :** |  |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| **Principal Investigator’s signature** |  | **Date signed** |
|  |  |  |
| **Supervisor’s signature and stamp** |  | **Date signed** |
|  |  |  |
| **Dean of Faculty/Head of Department’ signature and stamp** |  | **Date signed** |

**FOR FOM IACUC OFFICE USE ONLY**

**Decision of Faculty of Medicine Institutional Animal Care and Use Committee (FOM IACUC)**

|  |
| --- |
| ☐ Approved |
| ☐Approved Pending Minor Modification |
| ☐ Withhold Approval Pending Justification and Clarification |

This AUP form has been reviewed by the FOM IACUC, and is approved based on the information provided.

Remarks:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Signature of FOM IACUC Chair: Date:

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| --- | --- |
| Date of AUP Approval: |  |