



**IPHARM ANIMAL ETHICS COMMITTEE (IPAEC)
MALAYSIAN INSTITUTE OF PHARMACEUTICALS AND NUTRACEUTICALS
MINISTRY OF SCIENCE, TECHNOLOGY AND INNOVATION**

**Application for Ethics Approval for Research Projects and OECD-GLP Pre-Clinical Studies Involving
Animals**

1. Please complete the application form in accordance to the IPAEC Guidelines. Incomplete application will be returned to the applicant and 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 study.
3. Application must be word-processed or typewritten.
4. Please submit the application and direct all enquiries to the following address:

The Secretary, Animal Ethics Committee (IPAEC), Malaysian Institute of Pharmaceuticals and Nutraceuticals, Ministry of Science, Technology and Innovation (MOSTI), Lot 136 (JBG 51/2), Jalan Bukit Gambir, 11700 Gelugor, P.Pinang (Tel: 04-6563030; Fax: 04-6563021)
Email: zulkhurnain.utar@gmail.com

GENERAL INFORMATION

- The investigator is responsible to ensure that all facets of animal care and use meet the requirements of the **IPAEC POLICY AND CODE OF PRACTICE FOR THE CARE AND USE OF ANIMAL FOR SCIENTIFIC PURPOSES.**
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- The Code of Practice embodies the principles of:
 - 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 application should be presented in a way that the uses of animals are explained in detail from the beginning to the completion of a project. The investigator should provide a step by step examination of all treatments (substances, dose rates, routes, volumes, anaesthetics, surgical procedures etc) and the expected effects. Flow charts or sequence of events tables are often of assistance. In addition, factors that will impact on animals such as housing (type, duration, opportunity for social interaction) should be considered.
- 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.

IPAEC File No:

Date:

SECTION 1: OVERVIEW OF PROJECT**1. Name of Principle Investigator**

1.1 Name

1.2 Position/Division

1.3 Address for correspondence

1.4 Tel. No

1.5 Email

2. Title of Project**3. Objective of the project (summary)****4. Provide a brief background and justification of the project (not more than 300 words)**

5. Provide a summary of the study design / protocol involving the animals. Please attach a separate document if necessary.

5.1 Please specify the handling and methods of treatment (simplify with flow chart if necessary)

5.2 Please specify surgical procedure

5.2 Please specify sampling and details

6. Types of Project (please tick)

- | | | |
|-----|---|--------------------------|
| 6.1 | Research | <input type="checkbox"/> |
| 6.2 | Pre-clinical studies | <input type="checkbox"/> |
| 6.3 | Postgraduate Project (PhD, Masters etc) | <input type="checkbox"/> |
| 6.4 | Other, please specify | <input type="checkbox"/> |

7. Project Duration

- | | | |
|-----|--------------------------------------|----------------------|
| 8.1 | Proposed starting date (dd/mm/yy): | <input type="text"/> |
| 8.2 | Proposed completion date (dd/mm/yy): | <input type="text"/> |
| 8.3 | Duration of project: | <input type="text"/> |

8. List all personnel who will be participating in the animal components of the project. Please provide a copy of relevant experiences or training certificate(s) pertaining to the above.

No.	Name	Role	I/C / Passport No.	Contact No.	Signature & Date
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					

SECTION 2: JUSTIFICATION FOR ANIMAL USE
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1. Reasons for animal use. The answers provided are crucial for the assessment of the scientific merit of the project and the justification of animal use

1.1 Explain why is it necessary to use animals in this experiment

1.2 Explain if alternatives to animals have been considered

1.3 Provide the species, the scientific and common name, strain, age, sex and weight of the animals (if applicable) and explain why these criteria were chosen

Species (scientific and common name)	
Sex	
Body weight	
Age	
Name and address of supplier	
Justification for selection of the study species	

2. Number of animals**2.1 How many animals will be required? (please fill up the table)**

No.	<i>Scientific and Common Name</i>	Male (No.)	Female (No.)	Total (No.)
1.				
2.				
3.				
	Grand Total			

2.2 Explain why the number of animals will be required

SECTION 3: ETHICAL CONSIDERATIONS
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1. Assessment of the impact on animal well-being

1.1 Provide step by step information on what happens to the animal(s) from the time the project starts until the time the project ends.

2. Impact

2.1 Identify all factors and procedures that may have an impact on an animal's well-being. This may include handling, housing, specific experimental procedures etc. Describe measures on how to minimize any adverse effects as a result of the above factors. Detailed out the measures such as treatment substances, dose, route of administration, anaesthetic and analgesic regimen etc.

3. Source

3.1 Sources of animals (Address of Source/Supplier)

3.2 Permits required (If protected native species, provide details of appropriate permits held)
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3.2.1 Holder:	
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3.2.2 Issuing Agency:	
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3.2.3 Date of Issue:	
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3.2.4 Serial No.:	
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3.2.5 Period of Validity:	
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4. Animal housing, monitoring and management

4.1 Housing location of the animals

4.2 Describe the type of housing and housing conditions

Temperature	
Humidity	
Air renewable	
Light	
Animal cage and size	
Cleaning:	
Rooms	.
Cages	.
Food containers and water bottles	

4.3 Describe the maximum and minimum number of animals per cage/pen

4.4 Environmental enrichment (Please indicate type(s) of environmental enrichment (special/specific) to be used)

4.5 Describe the type of food, and the frequency of feeding

4.6 State the names, qualifications and experiences of the personnel whom will be monitoring the animals

4.6.1 During weekdays?

4.6.2 At night (if applicable)?

4.6.3 During weekends and holidays?

4.7 State the monitoring schedule including the frequency and methods during the experimental procedures and throughout the duration of the project

5. Experimental methods			
5.1 Procedures to be carried out on the animals: (Please tick)			
5.1.1 Surgery: <i>(If YES, answer 5.2 and 5.3)</i>	<input type="checkbox"/>	YES	<input type="checkbox"/>
5.1.2 Anaesthesia: <i>(If YES, answer 5.4 and 5.5)</i>	<input type="checkbox"/>	YES	<input type="checkbox"/>
5.1.3 Other: <i>(If YES, answer 5.6 and 5.7)</i>	<input type="checkbox"/>	YES	<input type="checkbox"/>
5.2 Outline the surgical procedures to be carried out on the animals			
5.3 Name the personnel who will be carrying out the procedures (Please provide a copy of relevant certificate(s) in handling laboratory animals)			
5.4 State the anaesthetic(s) to be used:			
5.4.1	Name:	 	
5.4.2	Dose:	 	
5.4.3	Route of Administration:	 	
5.4.4	Duration:	 	
5.4.5	Clinical signs to ensure anaesthesia are adequate:	 	

5.5 Neuromuscular Blocking Agent to be used (please tick):	<input type="checkbox"/> YES	<input type="checkbox"/>	<input type="checkbox"/> NO	<input type="checkbox"/>
<p>If YES,</p> <p>5.5.1 Agent:</p> <p>5.5.2 Dose:</p> <p>5.5.3 Route of Administration:</p> <p>5.5.4 Duration:</p> <p>5.5.5 Justification for use of neuromuscular blocking agent:</p>				
5.6 State the procedure				
5.7 Name the personnel who will be performing the procedure. Describe the relevant experiences				

5.8 Supervision during experimentation: (Detail the extent and method of supervision of animals during experimentation, including methods to be used for assessing and preventing pain and distress).

5.9 Describe post-procedural care. The investigator must provide detailed arrangements for immediate and continuing post-operative and / or post-procedural care, including restraint, housing and analgesics to be used

5.10 Post-procedural survival time for the animals: (hours / days / months / years)

6. Fate of animals

6.1 Animals to be sacrificed (please tick):

YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
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If YES

6.1.1 State the method to be used:

6.1.2 Name of the person performing euthanasia:

6.1.3 Method of disposal of euthanized animals:

6.1.4 If animals are not sacrificed, state what happen to them:

7. Hazardous Materials

7.1 Will hazardous agents be used in the animals (please tick):
If yes, proceed to 7.2

YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
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7.2 Types of hazardous agents

7.2.1 **Pathogenic organism**
Name of pathogen:

7.2.2 **Chemical carcinogen**
Name:
Dosage:
Route:
Frequency:

7.2.3 **Recombinant RNA / DNA**

7.2.4 **Radioactive material**
Name:
Dosage :
Shelf life:
Route:
Frequency:

7.2.5 **Other (please specify):**

7.3 Describe how hazardous agents are used.

7.4 Describe containment procedures.

7.5 Describe disposal of carcasses and waste.

8. Any Other Comments.

SECTION 4: DECLARATION BY PRINCIPAL INVESTIGATOR

I would like to declare that the use of animals in this project will conform to the **IPAEC POLICY AND CODE OF PRACTICE FOR THE CARE AND USE OF ANIMAL FOR SCIENTIFIC PURPOSES**. I will accept full responsibility for the conduct of all procedures detailed in this application and for the supervision of all personnel designated to perform such procedures.

I would like to confirm that all personnel have read this application and have agreed to comply with procedures described and any conditions imposed by the IPAEC.

Signature: Principal Investigator

Date

Certification of the IPAEC (Chairperson/Authorized Representative)

Name :

Signature : _____

Date :