****

****

**Application for Ethical Approval of New Research Protocol**

 **Basic data**

**Name:**

 **Phone:**

 **E-mail:**

**Department:**

**Protocol title:**

**Protocol purpose:**

* **Master phD Research Project**
* **Research derived from master thesis**
* **Research derived from phD thesis**

# The objective(s), hypothesis and outcomes of this protocol

Please list the objective(s), hypothesis and anticipated outcomes of the project

|  |  |
| --- | --- |
| **Objective(s)** |  |
| **Hypothesis** |  |
| **Outcomes and significance (benefits)** |  |

 **Procedural Ethics for Animal**

1. **Scientific aim of performing the research on animals:** ……………………………………………………………………………………..……………………………………………………………………………………………..………
2. **Identification of the animal species**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Species / Common name** | **Breed** | **Age** | **Sex** | **Number** | **Source** |
|  |  |  |  |  |  |

1. **Justification of animal use:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Minimum number of animals are used in this study (not exceed what experiment need)** | **Yes** | **No** | **N/A** |
| **Procedures taken to minimize pain (supported by references)****Reference**:……………………………………………………………… | **Yes** | **No** | **N/A** |
| **If chronic pain is expected by the end of the experiment, the animal will be sacrificed using approved method of euthanasia** | **Yes** | **No** | **N/A** |
| **Disposal of sacrificed animal will be consistent with health and environmental concerns** | **Yes** | **No** | **N/A** |

\*N/A (not applicable)

1. **Risks and Discomfort:**

A description of any reasonable risks or discomfort to the subjects …………………………………………………………………………………… ……..

# Replacement

This refers to the replacement of animals with non-sentient alternatives. Examples include the use of mathematical modeling and cell cultures. Replacement may also refer to the use of an alternative animal model whose well-being is more easily maintained compared to higher order species. An example is the replacement of a vertebrate species with an invertebrate species.

|  |  |  |  |
| --- | --- | --- | --- |
| **Authors have clear reason for rejection of any other techniques instead of animals** | **Yes** | **No** | **N/A** |
| **If authors used animal tissue only, can tissue be obtained from animals used for other projects?** | **Yes** | **No** | **N/A** |

1. **Reduction**

In this section authors are asked to provide information about the reasons why this number is necessary, whether there is an opportunity for sharing tissues or animals and strategies you have utilized to minimize the overall number of animals you plan to use.

|  |  |  |  |
| --- | --- | --- | --- |
| **Authors provide sample size calculation** | **Yes** | **No** | **N/A** |
| **Descripe**………………………………………………………………………………………………………………………………………………………………………………………… |
| **Authors provide experimental design** | **Yes** | **No** | **N/A** |
| **Descripe**………………………………………………………………………………………..………………………………………………………………………………………………… |
| **Animal re –use strategy** | **Yes** | **No** | **N/A** |
| **Descripe**………………………………………………………………………………………..………………………………………………………………………………………………… |

1. **Refinement**

This refers to the refinement of procedures to reduce the negative impact on animals. As well as refinement of experimental techniques the term refers to any additional measures used to enhance animal welfare, for example the provision of environmental enrichment items.

|  |  |  |  |
| --- | --- | --- | --- |
| **Authors done a pilot study** | **Yes** | **No** | **N/A** |
| **Authors follow animal housing instructions** | **Yes** | **No** | **N/A** |
| **Authors follow animal handling instructions** | **Yes** | **No** | **N/A** |
| **Anesthesia ( If yes, fill the table below)** | **Yes** | **No** | **N/A** |
| **Pain management ( If yes, fill the table below)** | **Yes** | **No** | **N/A** |
| **Blood and tissue sampling** | **Yes** | **No** | **N/A** |
| **Humane end point** | **Yes** | **No** | **N/A** |

**The Pharmacological agents and substances administered:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Agent/Substance** | **Drug**  | **Dosage** | **Frequency** | **Route administered** |
| **Anaesthetic agent** |  |  |  |  |
| **Post operative analgesic** |  |  |  |  |
| **antibiotic** |  |  |  |  |
| **Others** |  |  |  |  |

#  The experimental Agents

|  |
| --- |
| Experimental agents include investigational new drugs, tumor cells, stem cells, gene markers, radioisotopes, viruses and other biological agents, etc. |
| **Species** | **Drug/Agent** | **Dose (mg/kg body weight)** | **Vehicle** | **Route** | **Frequency** | **Duration** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

**Collection of biological samples**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type ofsample | Site ofcollection | Method ofsampling | Amount of sample (size/volume) | Frequency ofCollection(s) |
|  |  |  |  |  |
|  |  |  |  |  |

**Degree of pain severity**

Based on the experimental design and manipulated procedures in this study. Please check **ONLY** one box.

|  |
| --- |
| The most invasive or potentially painful procedure determines the pain severity level. |
| **No pain** | Animals being bred, acclimatized, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes. |
| **Minimum** | Animals that are subject to procedures that cause no pain or distress, or only momentary or slight pain or distress and do not require the use of pain‐relieving drugs |
| **Moderate** | Animals subjected to potentially painful or stressful procedures for which they receive appropriate anesthetics, analgesics and/or tranquilizer drugs. |
| **Severe** | Animals subjected to potentially painful or stressful procedures that are not relieved with anesthetics, analgesics and/or tranquilizer drugs. |

**Animal disposition**

|  |
| --- |
| **If animals are not to be euthanized at the completion of the protocol, please describe their ultimate use.**…………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………….**.** |
| **Identify and explain if any individual animal in this project will be used in any other project**…………………………………………………………………………………………………………………………………………………………………………………………………… |
| **What is the method of dead animal disposal?**…………………………………………………………………………………………………………………………………………………………………………………………………… |

**Safety**

|  |  |  |  |
| --- | --- | --- | --- |
| **Does this protocol involve the use of substances that may pose any health risk (infectious, carcinogenic or toxic) to humans and/ or animals (e.g. bacteria, viruses, fungi, parasites, primary cells, tissue, fluids, blood, recombinant DNA, chemicals, laser or radiation)?** | **Yes** | **No** | **N/A** |
| **If yes, please indicate the hazards that the agent(s) may pose to humans and/or animals and mention the precautions that will be followed to minimize health risk.**……………………………………………………………………………………………………………………………………………………………………………………………… |

|  |  |  |
| --- | --- | --- |
| **Agent** | **Route of administration** | **Method used to capture waste** |
|  |  |  |
|  |  |  |

**References lists**

………………………………………………………………………………………………………………………………………………………………………………………………

………………………………………………………………………………………………………………………………………………………………………………………………

………………………………………………………………………………………………………………………………………………………………………………………………

………………………………………………………………………………………………………………………………………………………………………………………………

**Statement of compliance**

I/we the undersigned have read the Animal care Guidelines and accept responsibility for the conduct of the experimental procedures detailed in this proposal in accordance with the guidelines contained in the Guide

**Authors**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Affliation** | **Phone**  | **E-mail** | **Signature** |
|  |  |  |  |  |
|  |  |  |  |  |

 **Head of the department**

 **Name**

 **Signature**

 **Date**