The Institutional Animal Care And Use Committee (IACUC) Alexandria university

Application FOR Approval To Use Animals In A Research Progect

Date application received:----------

Project Title IACUC Register Number

IACUC Permit Number

Principal Investigator:

Person to contact (if other than PI) for more details on environmental enhancement needs or restrictions for this protocol:

Research Staff Contact: ---------- Phone Number :

E-mail:

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Refer to the *Guide for the Care and Use of Laboratory Animals 8th Edition 2011 (the Guide).* 'Applicants' and Staff or Students of the Faculty of Science, Cairo University. Effective alternatives to using live animals must be considered. All use of animals for any purpose must be justified. Investigators have personal responsibility for all matters related to the welfare of the animals they use and must act in accordance with all requirements of them. *Guide*. This responsibility begins when an animal is allocated to a project and ends with its fate at the. completion of the project. Investigators have an obligation to treat animals with respect and to consider their welfare when planning and conducting projects.

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DECLARATION BY IACUC CHAIRMAN

I certify that this project has been considered and approved by the Department-Faculty of, Alexandria university lACUC on:

The period of approval for this project is

IACUC Chairman Name	IACUC Chairman Signature	Date

Project Title: Include a clear, descriptive and correctly spelled project title.

RELATED PROTOCOL

Has this or similar protocol been approved in the past?

☐ **NO** ☐ **YES**

If yes, provide previous protocol number and if necessary attach any documentation regarding questions and responses as well as any modification to procedures originally proposed.

Protocol Reference No:

OBJECTIVE/HYPOTHESIS : ***State the objective of this protocol or the hypothesis to be accepted or rejected***

Responsible investigator*:*

TITLE	FAMILY NAME	GIVEN NAME	QUALIFICATIONS	EMPLOYER

Co- Investigators:

TITLE	FAMILY NAME	GIVEN NAME	QUALIFICATIONS	EMPLOYER
f				

Research Duration from:

Funding sources:.....

Provide a Synopsis/Abstract in Layman's Language

On the first page of the ACUP Form, the PI is asked to provide a description of the proposed work that involves vertebrate animals *using language that a non-scientist could understand.* In other words, a high school student should be able to understand this portion of the protocol application. Scientific jargon should be avoided. IACUes are mandated by law to include a non-scientist member, as well as a member who is not affiliated with the University. Since *everyone* on the Committee should be able to clearly understand the intent and significance of the study, the IACUC will insist that this section of the protocol is appropriately written.

Literature Search for Duplication: This search must be performed to prevent unnecessary duplication of previous experiments *and (Reduction, replacement and refinement (3Rs) Alternatives):*

SEARCH TERMS:

Literature Source(s) Searched (Titles only):

1. **Data base**
2. **Books**
3. **Video**
4. **Other sources**

Date of Search:

Period of Search:

Key Words of Search:

Pre-search information:

Type of information	Description
Title of project	
Scientific outcomes	
Proposed animal model	
Proposed procedures on animal	
Potential causes of pain and distress in	
Any known species - specific consideration	

1.0 PROJECT CLASSIFICATION (Click a box and Check)

1.1 PROJECT PURPOSE

1.1.1 Primary purpose?

☐ Research ☐ Diagnostic ☐ Other (please specify)

☐ Teaching ☐ Product

1.1.2 Social relevance or significance?

☐ Conservation/Environment ☐ Veterinary Science ☐ Basic

☐ Medical Science ☐ Other (please

1.2 SUBJECT AREA

1.2.1 Main subject?

☐ Behavior ☐ Biochemistry ☐ Biomaterials

☐ Cell Biology ☐ Clinical sciences ☐ Drug

☐ Ecology ☐ Genetics/gene ☐ Immunology

☐ Molecular biology ☐ Parasitology ☐ Neurobiology

☐ Pharmacology ☐ Physiology ☐ Toxicology

☐ Embryology & comparative anatomy .

1.3 PROJECT CATEGORY

1.3.1. Does your study involve *in vitro* work that uses human cells/ tissues?

☐ NO ☐ YES

If yes, have you obtained from IRB?

☐ NO ☐ YES

If yes, please submit (RB approval.

***Ifyou have answered with "yes" , please do not continue the rest of this application**

1.3.2. CATEGORIES OF INVASIVENESS IN ANIMAL EXPERIMENT.

CATEGORY A

Experiments involving tissues without using live animals

☐ **NO** ☐ **YES**

If yes, please choose sources of the obtained tissues:

☐ commercially available animal cell lines.

☐ Euthanized animals from an approved protocol

☐ Cadaver Tissue from abattoir or purchased from the market

☐ cadaver collected from the field, e.g., road-kill.

☐ In case of, use of commercial or established animal cell lines for *in vitro* work only. Please complete the following

Type of cell line:

Name	Animal species	Source (Name and address of the supplier)

☐ in case of, use of animal tissues. Please complete the following:

1- Type of animal tissues requested:

Animal species	Tissue type	Quantity and frequency

Please describe how tissues or cadavers are packed, transported to the location where it will be used:

Packaging method:

Transportation (provide means and route) and safety procedures:

2- Source of animal tissue/cadaver:

☐ **commercial source/ abattoir**

Provide the name and address of the supplier

☐ **Dead animals collected from field (e.g. from car accident, etc ..)**

Provide the location and cause of death if known:

☐ **Euthanized animal from approved protocol. IACUC protocol number .....**

☐ **Other sources, please describe**

***If you have answered category A with "yes" , please do not continue the rest of this application.**

CATEGORY B

STUDIES OR EXPERIMENTS ON VERTEBRATES INVOLVING LITILE OR NO DISCOMFORT OR STRESS

These might include: holding of animals captive for observation or physical examination; blood sampling; injection of non-toxic material by the following routes; intravenous, subcutaneous, intramuscular, intraperitoneal, or oral, excluding intrathoracic or intracardiac; acute non-survival experiments in which the animals are completely anesthetized and do not regain consciousness, standard methods of euthanasia that induce rapid unconsciousness, such as anesthetic overdose or decapitation preceded by sedation or light anesthesia, short periods (few hours) of food and/or water deprivation.

☐ **YES** ☐ **NO**

CATEGORY C

STUDIES OR EXPERIMENTS ON VERTEBRATES INVLOVING MINOR STRESS OR PAIN OF SHORT DURATION

These might include: cannulation or catheterization of blood vessels or body cavities performed under anesthesia; minor surgical procedures under anesthesia, such as biopsies, laparoscopy; short periods of restraint consistent with minimal distress; overnight food and/or deprivation; behavioral experiments on awake animals that involve short-term, stressful restraint. These would not cause significant change in coat appearance, ocular or nasal discharges, abnormal respiratory or cardiac rate, and reduction of fecal or urinary output, isolation or crowding

☐ **YES** ☐ **NO**

CATEGORY D

STUDIES OR EXPERIMENTS ON VERTEBRATES THAT CAUSE MODERATE TO SEVERE DISTRESS OR DISCOMFORT.

These might include: Major surgical procedures conducted under anesthesia permitting recovery, with adherence to acceptable veterinary practices, adequate post-operative analgesia, fluid therapy and required veterinary nursing practices; exposure of animals to noxious stimuli for periods not above the minimal level required to demonstrate the required clinical effect' prolonged (several hours or more) periods of physical restraint applied in compliance with Committee on Animal Care guidelines; induction of behavioral stresses such as maternal deprivation, aggression, predatory-prey interactions, procedures which alter perceptual or motor functions which consequently affect locomotion and behavioral activity; immunization employing Freund's complete adjuvant administered subcutaneously or intramuscularly; induction of an anatomical or physiological deficit that will result in pain or distress; application of noxious stimuli from which escape is impossible; procedures that produce pain in which anesthetics are not used, such as toxicity testing with death as an end point; production of radiation sickness; certain injections, and stress and shock research that would result in pain approaching the pain tolerance threshold ..

☐ **YES** ☐ **NO**

CATEGORY E
PROCEDURES THAT INVOLVE INFLICTING SEVERE PAIN NEAR, AT, OR ABOVE THE PAIN TOLERANCE THERESHOLD OF UNANESTHETIZED, CONSCIOUS ANIMALS. **Such studies may not be confined to surgical practices, but may include exposure to noxious stimuli or agents whose effects are unknown; intradermal or foot pad injection using Freund's complete adjuvant; completely new biomedical experiments which have a high degree of invasiveness; behavioral studies about which the effects of the degree of distress are not known; use of muscle relaxants or paralytic drugs without the use of anesthetics; burn or trauma infliction on unaesthetized animals; a euthanasia method not approved by the** ☐ **YES** ☐ **NO**

1.3.2 USDA PAIN CATEGORY (Check one box)

☐ C: Routine Minimal, Transient, or No Pain and Distress.

☐ D:Pain, Distress Relieved by Appropriate Measures.

☐ E:Unrelieved Pain or Distress.

1.3.3 Are any of the following procedures involved? (Check one or more)

☐ IlAnalg~sia	☐ Behavioural deprivation	☐ Burns
☐ Foetal intervention	☐ Genetic manipulation	☐ Induction of serious disease
☐ Irradiation	☐ Malnutrition	☐ Others
☐ Neoplasia	☐ Toxicology	Please Specify

2.0 The Three R's

The 3 Rs refer to Replacement, Reduction and Refinement in practice it provides a framework for planning and evaluating the design of projects so that the best possible animal welfare outcome is achieved.

2.1 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.

Did the three Rs search determine any possible Replacement alternatives?

Replacement alternative category	No	Yes	If yes, describe and/or citation
Absolute replacement			
Relative replacement			
Others:			

Explain why techniques which do not use animals are unsuitable.

As the main aim of the work is to study the biological effect of MSC-derived microvesicles to enhanc wound healing in living animals

2.1.1. If requesting animal tissue only, can tissue be obtained from euthanized animals used for other projects? (Select and Check)

☐ **YES** ☐ **NO** **with IACUC approval no.** **/** **/** **/** IACUC.

2.1.2. ANIMALS REQUESTED

ANIMAL REQUIREMENTS:

Species	Strain	Age	WT	Sex (M, F)	Total Number	Source
						.

2.2 Animal reduction

This refers to the reduction in the number of animals used. This should never be at the expense of obtaining valid data. The concept can be considered more broadly to mean the use of the correct number of animals through correct application of experimental design and statistical analysis.

Did three Rs search determine any possible reduction?

In this section you are asked to provide information about the number of animals, 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.

Reduction alternative category	No	Yes	If yes, describe and/or citation
Experimental design			
Sample size calculation			
Animal model selection			.
Telemetry			
Animal re-use strategy			

2.2.1. Provide a justification for the numbers of animals requested including evidence that the numbers are minimal, but statistically robust to achieve the aims of the research. Include a table showing the numbers of animals to be used in treatments (and controls).

2.3. 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.

Did three Rs search determine any possible refinement?

Reduction alternative category	No	Yes	If yes, describe and/or citation
Animal handling			
Animal housing			
Anesthesia			
Analgesia/pain management			
Blood & tissue sampling			
Humane end point			

***Summary of Pharmacological Agents and Substances Administered:**

Agent/Substance	Drug	Dosage	Frequency	Route Administered
Anaesthetic Agent				
Post operative Analgesic				
Antibiotic				
Others:				

3.Materials and Methods:

Experimental Procedures & Summary

Experiment I:

Objectives and Purpose of Animal Use:

Briefly describe the objectives of the experiments proposed - that is, what you plan to achieve with the proposed project. Select one item that best describes the purpose of animal use in this proposal and enter the appropriate number into the box.

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Proposed Experiments

Enter a full description of the proposed experiments. The Proposed Experiments should provide a concise narrative description of the procedural events experienced by the animals in each experiment. If applicable to the proposed project, you should describe exactly what will be done to the animals in a step-by-step fashion. The Proposed Experiments should include specific details of all anaesthesia and analgesia, detailed surgical procedures performed, a complete description of all substances administered (including route, dose, volume and potential side effects). In addition, you should provide details as to the volumes and frequency of all fluids sampled or tissues collected, the parameters of any behavioural testing performed, a description of any conditions that may cause distress to the animals (including fasting, food/water restriction, altered environmental conditions, etc.), and a description of the primary method of euthanasia or an account of the final disposition of all the animals in the study. Include charts and diagrams to clearly show relationships between different activities and to demonstrate the distribution of animals between different procedures. This is especially important in projects where animals may receive more than one treatment or procedure. Note that final approval of the ACUP is dependent on a full and accurate account of which procedures are performed on which animals and on how many animals undergo each of the procedures.

Experiment 11:

Experiment Ill:
Experiment IV:

4. Death -as -an-Endpoint

Death -as -an-endpoint occurs when the death of an animal is the deliberate measure used for evaluating biological or chemical processes, responses or effects. That is, where the investigator will no intervene to kill the animal humanely before death occurs in the course of a scientific activity. It does not include euthanasia of the animal at the conclusion of an experiment or in order to carry our tests.

Does death as -an-endpoint form part of this research? ☐ NO ☐ YES

5.0 ETHICAL CONSIDERATIONS

.1 How long .will individual animals be held and/or subjected to experimental manipulations?

.....

5.2 How long will animals be held after they recover from experimental procedures?

.....

5.3 Is this a repetition of a previous experiment? If yes, please justify the repetition of this experiment.

.....

5.4 Have, or will, any of the animals be used in other experiments?

If yes,. .please give IACUC register number (if known) and justify their use in this project.

☐ NO ☐ YES

5.5 Does this experiment pose any health risk to staff or other animals?

If yes, how will this health risk be minimized?

☐ NO ☐ YES

5.6.1 What will happen to the animals at the completion of this project?
Animals will be properly treated and kept without any general health disturbances

5.6.2 If animals are to be killed, how will this be done?

5.6.3 What will be the method of disposal of dead animals?

6.0 SUPERVISION OF EXPERIMENT AND CARE OF ANIMALS

6.1 Who will conduct the experiments and maintain the animals?

Responsible Investigators, Lecturers or Supervisors	
Assistant Investigators, Postgraduate Students or Demonstrators	
Animal Facility Supervisor	
Proposed Analgesic (dose rate and regime)	

6.2 Experimental *j* Collecting Locations

Specify intended Animal Housing Facility or Wildlife Sampling Areas to be used	

6.3 Animal Housing Requirements. (Select and check)

Micro environment	Housing Cage type Bedding Feeding Watering	☐ Group ☐ Conventional ☐ Normal ☐ Normal ☐ Normal	☐ Individual ☐ IVC ☐ Micro-isolator ☐ Special ☐ Special diet ☐ Special regime ☐ Supplemented ☐ Special regime
Macro environment	Temperature Humidity Containment	☐ Ambient ☐ Ambient ☐ Normal	☐ Other (Details .....) ☐ Other (Details .....) ☐ Other (Details .....)

6.4 Technical J Training requests (Select and check)

Will Staff be requested to perform technical work on animals in addition to routine husbandry?	☐ NO	☐ YES
Will Staff be requested to provide training in any techniques required?	☐ NO	☐ YES

Animal Facility Supervisor (signature):

7.0 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.

7.1 Responsible Investigators, Lecturers or Supervisors

Name	Phone	E-mail	Signature

7.2 Assistant Investigators, Postgraduate Students or Demonstrators

Name	Phone	E-mail	Signature

7.3 FACULTY RECOMMENDATION

Head of Department **Date**