L-Università ta' Malta

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Joint FREC Animal Research Sectoral Sub-committee

General Information and Instructions

The Joint FREC Animal Research Sectoral Sub-committee (JFARSS) is required by international and local regulations to review all projects (research, teaching, or other) involving the use of live, vertebrate animals. This includes any new or competitive renewal research proposal, as well as the use of live vertebrate animals in teaching demonstrations and/or student laboratory studies.

The JFARSS advices the respective FRECs regarding specific projects that entail the use of animals in research. JFARSS also advices and assures UREC, and through it, the Rectorate, that animal welfare is in conformity with national legislation, specifically the *Animal Welfare Act* (Cap.439, as amended) and the *Protection of Animals Used For Scientific Purposes Regulations* (Legal Notice 161 of 2017) as well as that of EU legislation (Directive 2010/63/EU). Through the Animal Welfare Act and upon recommendation from Senate, JFARSS is empowered as the principal administrative institutional 'Animal Welfare Committee' to assess animal care, treatment and practices in experimental research.

The JFARSS is to ensure that the research carried out is within the provisions of the national Protection of Animals Used for Scientific Purposes Regulations, LN161/2017 and the EU directive 2010/63/EU so that the following tasks are followed:

a. scrutinize experimental protocols and methodologies in research projects dealing with the use of live animals;
b. advise the staff dealing with animals on matters related to the welfare of animals, in relation to their acquisition, accommodation, care and use;
c. advise the staff on the application of the requirement of replacement, reduction and refinement, and keep it informed of technical and scientific developments concerning the application of that requirement;
d. establish and review internal operational processes as regards monitoring, reporting and follow-up in relation to the welfare of animals housed or used in the establishment;
e. follow the development and outcome of projects, taking into account the effect on the animals used, and identify and advise as regards elements that further contribute to replacement, reduction and refinement; and
f. advise on rehoming schemes, including the appropriate socialisation of the animals to be rehomed;
g. keep minutes and records of all submitted projects for a period of FIVE years;

Approval of a protocol by the JFARSS

Please type and complete all of the applicable sections. All correspondence including submission of this form is to be emailed to **Ms Graziella Azzopardi, Centre for Molecular Medicine & Biobanking, University of Malta** (graziella.azzopardi@um.edu.mt) **and one copy to the JFARSS at the email: jfarss.research@um.edu.mt.**

When completing the summary portion of the protocol, please state the general scientific purpose, contribution to improvement of the quality of life, and the expected significance of the proposed study. Include the major thrust of the experimental procedures, e.g., antibody production, ablation behavioural studies, surgical removal, etc., and give details such as names of anaesthetics, analgesics, tranquilizers, etc. Experimental design and science will be reviewed only as relevant by the JFARSS.

When specifying the number of animals to be used, please ensure the numbers are as accurate as possible. You are encouraged to expand your writing within the boxes provided as necessary.

UNIVERSITY OF MALTA

ANIMAL STUDIES PROTOCOL FORM - Appendix A

** All sections must be duly filled. Failure to do so will result in this application being considered as a null and void. Please expand as necessary within the boxed sections provided.*

PROJECT TITLE

PERSONAL DETAILS OF APPLICANT

Title (e.g. Professor, Dr, Mr, Ms):	
Surname:	
Forename(s):	
Date of Birth *(dd, mm, yyyy)*:	
Academic qualifications:	
Position/appointment/student: (if student, please specify if this study is undertaken at undergraduate, graduate or postgraduate level)	

CONTACT DETAILS

Address for correspondence: *(This will normally be the address of the establishment where you are working)*	
Telephone number and extension:	
Mobile phone number (optional):	
Fax number:	

E-mail address:	

DURATION OF PROJECT

Specify the duration of the project/study undertaken	

PLACE(S)

Under JFARSS, a project must specify a place or places (so-called 'availabilities') where the regulated procedures will be carried out.

Primary availability

Room number(s)

PROPOSED ANIMAL STUDY

Under the EU Directive 86/609/EEC and later replaced and updated by EU Directive 2010/63/EU the protocol for the use of animals in research must authorise the application of specified regulated procedures to animals of specified descriptions (https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:en:PDF).

a. Significance of the study:
b. Specific scientific or clinical questions addressed:
c. General goals and experimental design:

ENDANGERED / PROTECTED SPECIES

Does the study involve the use of endangered or protected species? Yes ☐ No ☐

If you intend using an endangered or protected species, explain why the purpose of the programme cannot be achieved without their use.

A. ADMINISTRATION OF PROJECT

1. Funding: Departmental ☐ Faculty ☐ University ☐

   If other, please specify:

   a. Start date:

   b. End date:

   c. Grant vote number (if applicable):

2. If the animal protocol will be (has been) reviewed by institutions other than the University of Malta, please supply the names of these institutions, and submission dates/approval dates:

3. Is this protocol part of a Grant? Yes ☐ No ☐

   If yes, please list title of the overall project:

4. Is this protocol a new submission? Yes ☐ No ☐

5. Laboratory personnel responsible for daily supervision of animal use and procedures for this project.

By law, experiments shall be performed by competent authorized personnel who regularly work on animal procedures, or receive their training under the direct supervision of such a person/s with a proven track record of uninterrupted practice in the use of particular techniques pertinent to the stated animal species.

Name and Surname:

Job title:

Role in project:

Office Phone Number:

Mobile Phone Number:

E-Mail Address:

6. List all additional personnel involved in the project including their specific role in the project. *Record in the order to be called in emergencies.*

Name and Surname	Mobile Number	Role in Project	Signature

7. Indicate the buildings and rooms in which:

a. Experimental procedures will be performed:

b. Surgical procedures will be performed:

c. Postoperative recovery (after survival surgery):

d. Housing facility:

8. The JFARSS strongly discourages housing of animals outside of the central animal holding facilities for more than 12 hours. If you wish to house outside an approved facility, state

desired housing and provide justification. The committee will evaluate requests on a case by case basis.

B. JUSTIFICATION FOR THE USE OF ANIMALS, SPECIES USED AND NUMBER OF ANIMALS REQUESTED PER YEAR (The 3Rs).

Animals are only used when the answers to scientific questions cannot be obtained in any other way. Alternatives to the use of animals in research must be sought whenever possible. Please provide a rationale for involving live animals in view that other alternatives have been considered, including the appropriateness of the animal species. What alternatives have you considered and why are they not suitable?

Indicate the number of animals to be used in these experiments inclusive of the number of experimental animals needed per group (if any).

What measures have been or will be taken to ensure that the minimum number of animals will be used in this project?

Explain your choice of species, model(s) and method(s). Explain why they are the most refined for the intended purpose?

C. VIDEOS/PHOTOGRAPHS

Will videos or photographs be taken during experiments? Yes ☐ No ☐

If yes, please provide justification. State procedure to be photographed, justify necessity of using photographs, and state where they will be developed and stored.

D. EUTHANASIA

The policy dictates that animals which appear in severe pain or distress or are moribund be euthanized unless their continued existence is scientifically justified.

1. State the technique used for performing euthanasia on each species. Be specific regarding euthanasia agent, dosage and route of administration. If proposed method of euthanasia does not conform to established guidelines, please provide justification as an attachment.

2. If the experiment involves lethal challenge with death as a dependent variable, please provide justification as an attachment. Explain necessity of allowing animals to die, as opposed to euthanizing moribund animals.

3. If death is dependent as an outcome variable, please provide justification.

E. NON-SURGICAL PROCEDURES (For Surgical Procedures, Complete Section F)

1. For non-surgical procedures, describe all procedures and experimental manipulations to be employed in your animal experiments.

2. Will any of the following be performed: immunizations; biological fluid collections (blood, lymph, bile, CSF, etc.); tumour passage or induction; human tissue; and/or the use of biohazardous agents (infectious agents, radionuclides, toxic agents, carcinogens, or recombinant DNA)? Yes □ No □
   If yes, please complete Schedule B.

3. Are any animals subjected to significant stress (physical restraint >4 hours, or food/water deprivation >18 hours)? Yes ☐ No ☐
   If yes, please describe procedure in detail.

4. List any anaesthetics, analgesics or neuromuscular blocking agents which will be used during non-surgical procedures. For each species please list agents, dosage and route of administration.

5. If chemical relief of pain and discomfort is to be withheld from the animal, please indicate the experimental endpoint and provide justification for not relieving pain and distress as an attachment.

6. Provide justification for the use of neuromuscular blocking agents. Indicate explicitly the manner in which adequacy of anaesthesia will be assessed as a separate attachment.

F. SURGICAL PROCEDURES

Table F The procedures and animals for which you seek authority (Please continue on additional sheets if necessary)			
Category	**Procedure**	**Animal species**	**Tick if appropriate** *(Tick Appropriate Box)*
A	Minor/minimally invasive procedures not requiring sedation, analgesia or general anaesthesia		☐
B	Minor/minimally invasive procedures involving sedation, analgesia or brief general anaesthesia Plus - surgical procedures conducted under brief non-recovery general anaesthesia		☐
C	Surgical procedures involving general anaesthesia. Plus – administration and maintenance of balanced or prolonged general anaesthesia		☐
D	Other (Please provide details) (i) details……		☐

1. <u>For Survival Surgical Procedures</u>

   a. For each species describe in detail the surgical procedures to be used, specifically: presurgical preparation, anaesthetic regimen (drugs, dosage and route of administration), surgical technique, and postoperative care.

   b. List probable clinical responses to and potential complications of the operations. Indicate how these complications will be managed.

   c. If chemical relief of pain and discomfort is to be withheld from the animal, please indicate the experimental endpoint and provide justification for not relieving pain and distress.

   d. If multiple major survival operations are planned, identify explicitly the medical and/or scientific aspects of the investigation that require the performance of multiple major survival operations on particular animal subjects.

   e. If neuromuscular blocking agents are to be used during surgery, provide justification for the use of neuromuscular blocking agents. Indicate explicitly the manner in which adequacy of anaesthesia will be assessed.

2. For Non-survival Surgical Procedures

a. For each species describe in detail the surgical procedures to be used, specifically: presurgical preparation, anaesthetic regimen (drugs, dosage and route of administration), surgical technique, and postoperative care.

b. List probable clinical responses to and potential complications of the operations. Indicate how these complications will be managed.

c. If chemical relief of pain and discomfort is to be withheld from the animal, please indicate the experimental endpoint and provide justification for not relieving pain and distress.

d. If multiple major survival operations are planned, identify explicitly the medical and/or scientific aspects of the investigation that require the performance of multiple major survival operations on particular animal subjects.

e. If neuromuscular blocking agents are to be used during surgery, provide justification for the use of neuromuscular blocking agents. Indicate explicitly the manner in which adequacy of anaesthesia will be assessed.

G. INVESTIGATOR ASSURANCE

1. Alternatives to the use of animals and procedures that cause more than momentary pain or distress have been considered. The proposed study does not unnecessarily duplicate previous experimentation. Databases and literature resources surveyed to establish these statements include: (check those that apply):

    - ☐ Library Resources
    - ☐ Biological Abstracts
    - ☐ Current Contents
    - ☐ Medline
    - ☐ Primate Information Centre

2. The information provided in the protocol for the proposed project gives an accurate picture of the intended use and care of animals employed in this research and/or teaching activity ☐
3. Changes in animal care and use procedures will not be implemented unless approved by the JFARSS ☐

4. Unless otherwise approved by the JFARSS, provisions of the Animal Welfare Act, guidelines on humane care and use of laboratory animals, will be followed in the proposed project ☐

5. Anaesthesia, analgesia, sedation, tranquilization, and euthanasia will be used to relieve pain or distress, so long as these agents do not compromise the validity of the experimental data taken ☐

6. Appropriate steps have been and will be taken to avoid or minimize exposure of persons working with animal subjects to any hazardous agents used in the project ☐

7. All staff involved with this project have received information and training on the care and use of laboratory animals ☐

8. All staff involved with this project have been informed of the University of Malta Occupational Health Program ☐

DECLARATION BY THE PRINCIPAL INVESTIGATOR (APPLICANT)

a. I understand the terms and conditions under which I can conduct these experiments under the Council Directive 2010/63/EU, and I have read all relevant regulations on the operation of the legislation ☐

b. I understand that I am guilty of an offence if for the purpose of obtaining a licence under this Act I furnish information which I know to be false or recklessly furnish information which is false or misleading ☐

c. I confirm that I have read and understood the Animal Welfare Act 161/2017 on the protection of animals used for scientific purposes ☐

SIGNATURE ---------- DATE ----------

For official use only

_____ _____

Veterinarian signature Date

_____ _____

Chairperson's signature Date

PROJECT PROPOSAL (please expand as necessary within the boxed outline below)

METHODOLOGY (inclusive of experimental protocols)

(please expand as necessary within the boxed outline below)