Local Committee of Bioethics (HAP-09-A-043)
Experimental Animal Use Protocol

Email: lcbe@nbu.edu.sa

Administrative Use

Date Submitted	
Application Type	☐ New ☐ Renewal ☐ Amendment
Review Type	☐ Full Committee ☐ Expedited ☐ Other: _____

PART A – PROJECT AND PERSONNEL INFORMATION

Project Title	
Principal Investigator (PI)	
Degree	
Department / College	
Institution	
Email / Phone	
Funding Source	
Project Start / End Date	_____ / _____

Research Team and Responsibilities

Name	ID	Department / College	Degree / Responsibility	Animal Training / Experience

PART B – ANIMAL INFORMATION

Species	
Strain / Stock	
Sex	☐ Male ☐ Female ☐ Both
Age / Weight Range	
Source / Supplier	
Total Number of Animals	
Number per Group	
Genetic Modification	☐ No ☐ Yes – describe: _____

Scientific justification for the selected species/strain, sex, age and number of animals:

_____

_____

_____

PART C – SCIENTIFIC JUSTIFICATION AND STUDY DESIGN

1. Scientific objectives and rationale:

_____

_____

_____

2. Literature review of the research (include relevant in-text citations):

_____

_____

_____

_____

3. Research methodology and overall study design:

Describe the overall experimental model, study sequence, controls, major stages of the research, and scientific rationale for the selected methodology. Do not repeat the detailed animal procedures requested in Part F.

_____

_____

_____

_____

_____

4. Potential risks, hazards, anticipated challenges, and contingency plans:

Describe foreseeable risks or challenges that may affect the conduct or outcome of the study and the planned measures to address them.

_____

_____

_____

5. Experimental groups / controls:

Group	Treatment / Experimental Condition	Dose / Route (if applicable)	n	Duration

6. Statistical justification / sample-size determination:

_____

_____

PART D – 3Rs: REPLACEMENT, REDUCTION AND REFINEMENT

Describe how alternatives to animal use were considered and the methods used to search for alternatives:

_____

_____

Literature/database search and/or expert consultation:

_____

_____

Replacement – Why are non-animal or less sentient alternatives not sufficient?

_____

_____

Reduction – How has the minimum scientifically justified number of animals been determined?

_____

_____

Refinement – What measures will minimize pain, distress and adverse effects?

_____

_____

PART E – HOUSING, HUSBANDRY AND VETERINARY CARE

Animals will be housed in an approved institutional animal facility. ☐ Yes ☐ No ☐ N/A

If outside the institutional facility, provide justification, exact location, responsible personnel and approval documentation:

_____

_____

Housing Location	
Cage / Pen Type and Density	
Bedding / Environmental Enrichment	
Food and Source	
Water and Source	
Light / Temperature / Humidity	
Veterinary Care / Responsible Veterinarian	

PART F – ANIMAL-RELATED PROCEDURES

Describe each procedure performed directly on the animals. Include the p**rocedure, substance/device, dose or amount, route/site, frequency, duration, sequence, and relevant handling or restraint**. Do not repeat the overall study design described in Part C.

_____

_____

_____

_____

_____

Administration of drugs/substances or other interventions:

_____

_____

Sample collection or other invasive/non-invasive manipulations:

_____

_____

Will any procedure involve restraint? If yes, describe the method, duration and frequency. ☐ Yes ☐ No ☐ N/A

_____

Will any procedure cause pain or distress? If yes, describe the procedure and expected impact. ☐ Yes ☐ No ☐ N/A

_____

PART G – PAIN, DISTRESS AND SEVERITY

Animals are expected to experience pain or distress. ☐ Yes ☐ No ☐ N/A

Expected severity: ☐ None ☐ Mild ☐ Moderate ☐ Severe

Describe the source, expected duration and severity of pain/distress:

_____

_____

Describe measures to prevent, minimize or relieve pain/distress:

_____

_____

If analgesia/anesthesia is not used where pain is expected, provide scientific justification:

_____

_____

PART H – ANESTHESIA AND ANALGESIA

Anesthesia will be used. ☐ Yes ☐ No ☐ N/A

Agent(s), dose, route, frequency and duration:

_____

_____

Method used to assess depth of anesthesia:

_____

_____

Analgesia will be used. ☐ Yes ☐ No ☐ N/A

Agent(s), dose, route and schedule:

_____

_____

Monitoring during anesthesia and recovery:

_____

_____

PART I – SURGICAL PROCEDURES

A surgical procedure will be performed. ☐ Yes ☐ No ☐ N/A

Type: ☐ Survival ☐ Non-survival

Species, surgical title and detailed procedure:

_____

_____

_____

Location of Surgical Procedure (College/Building/Room number):

_____

_____

Name of surgeon(s):

_____

_____

Aseptic technique (for survival surgery):

_____

_____

Post-operative care and monitoring:

_____

_____

PART J – ANIMAL MONITORING AND HUMANE ENDPOINTS

Monitoring frequency: ☐ Daily ☐ Twice daily ☐ More frequently: _____

Parameters to be monitored:

☐ Body weight / weight change

☐ Food and water intake

☐ Activity and behavior

☐ Posture / gait / mobility

☐ Respiration

☐ Appearance / grooming

☐ Signs of pain or distress

☐ Other clinical parameters: _____

Humane endpoints / criteria for removal from the study:

_____

_____

_____

Person responsible for monitoring and escalation:

_____

_____

PART K – EUTHANASIA

Euthanasia will be performed as part of the study. ☐ Yes ☐ No ☐ N/A

Method, agent, dose/route where applicable:

_____

_____

Method used to confirm death:

_____

_____

If euthanasia is not planned, explain final disposition of animals:

_____

_____

PART L – BLOOD COLLECTION

Blood will be collected during the study. ☐ Yes ☐ No ☐ N/A

Species / purpose / frequency:

_____

_____

Frequency	Volume	Method	Anatomical Site

PART M – BIOLOGICAL MATERIALS

Biological materials introduced into animals must be appropriately screened/tested for relevant infectious agents or pathogens, as required by institutional biosafety and animal facility policies.

Biological materials (cells, tissues, tumors, body fluids, etc.) will be introduced into animals. ☐ Yes ☐ No ☐ N/A

If Yes, specify:

- **Type of biological material:** _____
- **Species/source:** _____
- **Purpose:** _____
- **Method/route of administration:** _____
- **Pathogen testing / screening performed:** ☐ Yes ☐ No ☐ N/A
- **Relevant documentation attached:** ☐ Yes ☐ No ☐ N/A

PART N – DIETARY OR FLUID MANIPULATION

Food or fluid will be restricted or otherwise manipulated. ☐ Yes ☐ No ☐ N/A

Describe the manipulation, duration, scientific rationale and potential effects:

_____

_____

Monitoring frequency and measures to minimize adverse effects:

_____

_____

PART O – BREEDING

Animals will be bred for this protocol. ☐ Yes ☐ No ☐ N/A

Scientific justification; species/strain produced; breeding plan:

_____

_____

Disposition of surplus animals:

_____

_____

PART P – ANTIBODY PRODUCTION / OTHER SPECIAL PROCEDURES

Polyclonal antibody production will be performed. ☐ Yes ☐ No ☐ N/A

Species, antigen, adjuvant, injection and antibody harvesting procedures:

_____

_____

Monoclonal antibody production will be performed. ☐ Yes ☐ No ☐ N/A

Method, species, number of animals and euthanasia criteria:

_____

_____

PART Q – TRAINING, COMPETENCY AND OVERSIGHT

All personnel involved in animal research must meet the institutional training and competency requirements applicable to their role. Personnel who physically handle animals or perform animal procedures must provide evidence of appropriate animal care and use training before initiating animal procedures.

1. Principal Investigator (PI):

☐ NCBE Research Ethics Certificate attached ☐ Other institutionally approved ethics training:
_____

2. Personnel who will physically handle animals or perform animal procedures:

☐ Animal Care and Use / Laboratory Animal Handling Training Certificate attached

Training provider: _____ Course title: _____

3. Procedure-specific training/competency (when applicable):

☐ Attached ☐ Not applicable

Procedure(s) requiring specific competency: _____

4. Training records:

☐ Certificates attached ☐ Training records attached ☐ Pending – explanation: _____

5. Veterinary consultation / oversight arrangements:

_____

_____

PART R – ATTACHMENTS CHECKLIST

☐ NCBE certificates

☐ Investigator CVs

☐ Training Certificates / Records

☐ Biological-material testing documentation, if applicable

☐ Other supporting documents: _____

PART S – INVESTIGATOR DECLARATION

I certify that the information provided in this application is accurate and complete. I confirm that the proposed animal procedures will be conducted only after the required institutional approval has been obtained and in accordance with approved institutional policies, applicable ethical requirements, and the principles of Replacement, Reduction and Refinement.

Principal Investigator Name: _____

Signature: _____ Date: _____

Department/Institutional Approval (if applicable): _____