|  |
| --- |
| *Please contact the Comparative Medicine Department (ext. # 31795/77672/24780) for assistance in completing this form. The form can be downloaded from* [*the Office of Research Affairs (ORA) site.*](file:///C%3A%5CUsers%5Cf41219%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CTemporary%20Internet%20Files%5CContent.IE5%5C3KKVOWBL%5C%28https%3A%5Cwww.kfshrc.edu.sa%5Cen%5Chome%5Cresearch%5Csubmission%5Crac%5Cstudies%29) *The completed application should be submitted to ORA together with the research proposal or request to use animals for training purposes.* |
| SECTION I - APPLICATION FOR USE OF ANIMALS IN RESEARCH, TESTING AND/OR TRAINING |
| 1.Type of Application: [ ]  New Application [ ]  Renewal (for more than 3 years ongoing projects); RAC #: [ ]  Amendment:  |
| 2. Proposal Title: | **Duration of the study:** |
| 3. Rationale, Goals, and Animal Research Methodologies: (Please describe briefly but accurately the methodology of experiments involving animals). |
| 4. Species and Number of Animals to be used: *(*Please list all species to be used for the project (according to the standard nomenclature *(http:// www. Informatics.jax.org/mgihome/nomen/).* For each species indicate the strain, age, sex, weight, and the number you estimate will be needed for each years and for the entire project). |
| Species | **Strain** | **Age** | **Gender** | Weight |  **No. of Animal Per Years** | **Total****No.** | **Duration** |
|  **1st** |  **2nd** |  **3rd** |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
| 5. Justification of using animals: *(Please explain why it is necessary to use animals, why the particular requested species are needed, and how the number of animals was calculated. Address issues of statistical analysis, data variability, and sample size calculations).*    |
| 6. Location:a. Where will the animals be housed?   |
| b. Where will the animal studies be conducted? |
| c. Will animals be housed outside the animal facilities for over 10 hours? *(Please justify)*  |
| 7. Will this project involve the use of any of hazardous material?[ ]  Yes [ ]  No If yes, please complete the Biological, Chemical & Radiological Hazards Form *(Downloaded from* [*ORA*](http://rc.kfshrc.edu.sa/rac/) *site)* |
| 8. Will any of these animals will be used in more than one project?[ ]  Yes [ ]  NoIf yes, please indicate the RAC number(s) of the other project(s) and explain why. |
| 9. Animal Wellbeing, Pain and Distress: Indicate any aspect of the research project that has the potential to produce pain. Please grade pain/distress categories according to ACUC guidelines [*(Quick Flow Chart)*](http://www.kfshrc.edu.sa/RC/ACUC_Guidelines_Jun_11_06.pdf). a. Please select pain and distress category: [ ]  Category A [ ]  Category B  [ ]  Category C [ ]  Category Db. Justifications for Category C and D:c. For pain and distress category B and C; *please Indicate your plan for reducing pain or distress through* *use of sedatives, anesthetics, or analgesics and use the following table to list all medications* |
|  Type of Medication |  **Dose** | **Route of Administration** |  **Frequency** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| d. Does study protocol include withholding of water and feed: [ ]  Yes [ ]  No If yes (*please explain and justify*)e. Will animals be subjected for prolonged physical restrain:[ ]  Yes [ ]  No If yes, *please explain and justify* |
| f. Are you creating a novel animal model (i.e. genetically engineered, feeding animals special diet,establishing novel procedure, injecting novel biological, etc.)[ ]  Yes [ ]  No If yes, *please explain how animals will be monitored, personnel involved, frequency, etc.*) |
| 10. Animal Protocol Endpoints:a. Animal Experiment Endpoint (Clearly state what is experimental endpoint where aims and objectives of the animal study are accomplished for example, aging research, cancer growth, post-operative observation period, etc) |
| b. Humane Endpoint:Clearly state what is the humane endpoint where animals will be either eliminated and/or euthanized regardless of the experimental endpoint? |
| c. Euthanasia:Describe the method of euthanasia. If this requires administration of a drug, specify the dosage and route of administration. The method of euthanasia must be in accordance with the AVMA guidelines on Euthanasia *(*[*http://www.aphis.usda.gov/animal\_welfare/downloads/reports\_out/euthaasia.pdf*](http://www.aphis.usda.gov/animal_welfare/downloads/reports_out/euthaasia.pdf) *)*, unless the investigator provides written justification for any deviation based on scientific reasons. If animals will not be euthanized,what will happen to them? |
| 11. Alternatives to Use of Animals in research, testing and/or training: a. Are there alternative studies, procedures, or methods that could be conducted to answer the question of interest which would replace the need to use animals or reduce the number of animals needed?[ ]  Yes [ ]  No If yes, please explain why these alternatives are not being employed |
| b. Are there alternative studies, procedures, or methods that could be conducted which would lessen the pain or distress experienced by these animals? [ ]  Yes [ ]  No If yes, please explain why these alternatives are not being employed |
| c. Do these studies duplicate prior experimentation conducted by you or by others? [ ]  Yes [ ]  No If yes, please explain why the studies are still needed. |
| d. The RAC regulations require that you indicate the information sources you consulted to develop the rationale and methods for this study, to ensure that these studies do not duplicate previous studies and to ensure that there were no alternatives that would reduce the use of animals or lessen the amount of pain or distress they might suffer. Indicate which information sources were searched, when the search was last done, and what keywords were used for database searches. Sources might include: the animal welfare information center, the current research information service, midline, index medicos, current contents, specific journals, etc. |
|  Date of Most Recent Search |  **Sources Searched** |  **Keywords Used** |
|  |  |  |
|  |  |  |
| 12. Research team: (*please provide list of the research team who will be working with animals and/or animal**tissues and indicate their specific role, experience and training*)  |
|  Name |  **ID** |  **Qualification** |  **Experience/** **Training** |  **Role** | **Contact No** |  **Remarks** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| 13. Description for the Laymen: a. Potential Benefits to SocietyIndicate in laymen’s terms the potential benefits to society that may be derived fromthis research. Use plain English and avoid using scientific jargon and abbreviations.  |
| b. Pain/Distress:Describe in laymen’s terms the degree of pain or distress the animals are likely to experience by relating it as best you can to commonly understood medical, dental, or veterinary procedures. |
| SECTION II - COMPARATIVE MEDICINE BUDGET / CLEARANCE |
| 1. Animal Protocols and Flow Chart: Please describe the step by step protocol for all aspects of the project that involves the use of animals fromreceipt until disposition. This should include experimental groups, Administration of any drugs or special diet, and all surgery or other procedures to be performed on the animals. In addition, provide a flow chart(here or on a separate sheet) which summarizes the protocols using animals. |
| 2. Requested Support: Beyond routine care of animals, are there any special space and/or caging, special services, or support which are requested to carry on the project (e.g. veterinary assistance, help with anesthesia, equipment, monitoring, GLP Quality Assurance, etc.?) [ ]  Yes [ ]  No If yes, please describe |
| 3. ANIMAL BUDGET(To be completed by Comparative Medicine Department in Coordination with the Principal Investigator) |
| Item | **Subtotal** |
| Animal *(No. of animals x cost)* |  |
| Per diem*(No. of animals x per diem x days)* |  |
| Injectable anesthetics*(No. of vials x 150 SR)* |  |
| Inhalant anesthetics*(No. of bottle x 300 SR)* |  |
| Anesthetist time:*(No. of hours x 250 SR)* |  |
| Drugs and supplies*(No. of procedures x 200 SR)* |  |
| Blood Chemistry*(No. of samples x test cost)* |  |
| Hematology *(No. of samples x test cost)* |  |
| Serology*(No. of samples x test cost)* |  |
| Urine Analysis*(No. of samples x test cost)* |  |
| Histology *(No. of samples x test cost)*  |  |
| Laboratory supplies*(No. of samples x supplies cost)*  |  |
| X-Ray*(No. of procedures x procedure cost)*  |  |
| Echocardiogram*(No. of procedures x procedure cost)*  |  |
| C-arm fluoroscopy*(No. of procedures x procedure cost)*  |  |
| IVIS (Xenogen)*(No. of procedures x procedure cost)*  |  |
| Surgical instrument set*(No. of sets x 500 SR)*  |  |
| Sterile supplies*(No. of procedures x 300 SR)*  |  |
| Surgical theatre use*(No. of day x Theater cost)*  |  |
| Large animal post-operative care*(No. of days x 300 SR)*  |  |
| Small animal post-operative care*(No. of days x 100 SR)*  |  |
| Collection of specimens*(No. of animals x cost x frequency)* |  |
| Administration of drugs/biological*(No. of animals x cost x frequency)* |  |
| Others |  |
| Name of Chairman, Comparative Medicine Department: | **Signature:** | **Date:** |
| SECTION III - SURVIVAL SURGERY/PROCEDURE  |
| *Please contact the Comparative Medicine Department (ext. # 31795/77672/24780) for assistance in completing this form. The form can be downloaded from the Office of Research Affairs (*[*ORA*](http://rc.kfshrc.edu.sa/rac/)*) site. The completed application should be submitted to ORA together with the research proposal or request to use animals for training purposes.* |
| Are any animals to remain alive for any period of time after a surgical procedure? [ ]  Yes [ ]  No If yes, please complete the survival surgery/procedure form: |
| 1. Surgical Team: List members of the surgical team, including surgeon(s), technicians, and anesthesiologist. Indicate their training and experience with the species being used. |
| 2. Preoperative Preparation and Care: Describe pre-operative care and preparations, including physical examination, lab tests, antibiotics, etc. |
| 3. Surgical Procedure Description:  |
| 4. Anesthesia Plan: Describe your anesthesia/analgesia plan, including premedication, intraoperative anesthesia, and paralytics. List dosages, frequency and route of administration. State what criteria you will use to assess the level of anesthesia during surgery. |
| 5. Postoperative Analgesia Plan: Generally speaking, it is felt that major procedures require administration ofanalgesics for a certain period of time postoperatively. Describe your plan for evaluating and managingpostoperative pain or distress. Be specific in describing how you will evaluate pain and the frequency with whichassessment will take place. What drugs will be used for management of pain or distress? Give the dosage,route of administration, and frequency of administration.  |
| 6. Postoperative Recovery and care: Describe the postoperative recovery plan. Describe where recovery will take place, the personnel involved, how the animal will be monitored, and the specific criteria used to determine when the animal can safely be left unattended.  |
| I certify that all the information written in this form is correct and under my accountability.  |
| Principal Investigator:  | **Signature:** | **Date:** |