

# Policy & Guidelines for the Care and Use of Animals In Scientific Research

Vice Presidency of graduate Studies and Scientific Research, University Of Dammam

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### Policy for the Care and Use of Animals in Scientific Research

MESSAGE FROM H.E. PROF. ABULLAH AL-RUBAISH PRESIDENT, UOD



Recognizing that the use of animals has been a core component of scientific research to benefit humankind since antiquity, the University of Dammam (UOD) has committed significant resources for the development of the Center for Research and Medical Consultations, including its animal research facility, to advance its ambition to develop a robust and competitive research enterprise. Although only rodents and rabbits are currently used in research at UOD at this time, the facilities are sufficient to expand species on which such research can be conducted. Parallel with this entry into the use of animals in research, we are committed to establish and maintain high standards for the ethical care and use of all such species of living creature engaged in our research mission.

This Policy is an extension of policies and guidelines outlined in the Standing Committee for Research Ethics on Living Creatures (SCRELC) manual and embodies our commitment to: the ethical care and use of such animals in research; and, our provision of the required human and facility resources to assure our fulfillment of that commitment. Further, it is designed to develop an animal care and use program that is compliant with international standards, and, to allow our pursuit of such international accreditation. Our ambition is that our policies, guidelines and procedures for assurance of ethical care and use of animals for scientific research will become a benchmark for other programs within the Kingdom and the region.

### H. E. PROF. ABDULLAH M. AL RUBAISH

President, University Of Dammam



### Policy for the Care and Use of Animals in Scientific Research

MESSAGE FROM PROF DR. ABDULSALAM A. AL-SULAIMAN VICE PRESIDENT FOR GRADUATE STUDIES AND SCIENTIFIC RESEARCH, U0D



This policy for the care and use of animals in scientific research underscores the commitment to assure the humane treatment of all animals used in research at UOD. We recognize the obligations associated with using other species of living creatures for the purpose of improving the wellbeing of humankind and have developed this policy and its associated guidelines, rules and regulations with that responsibility in mind. Although only rodents and rabbits are currently used for research purposes at UOD, we have developed this policy with the knowledge and inclusiveness that it can be adopted for use with other species as well. As described in the policy, we also are committed to the three "R's" when using animals for research, which are:

- Restricting animal use in research to circumstances when the objectives of the research otherwise cannot be realized;
- Reduction of the number of animals used in protocols to the minimum required to achieve the aims of the research project; and,
- Refinement of research protocols to minimize pain and stress in animals used in research.

The Institutional Animal Care and Use Committee (IACUC) is tasked to see that these rules are followed in all protocols using animals for scientific research at UOD. We have used internationally accepted guidelines in the development of this policy with the explicit desire to ultimately achieve



international accreditation for our programs for care and use of animals in scientific research. Further, the detailed nature of this policy is designed to provide the IACUC, investigator, and the animal care personnel (veterinarian and staff) with the detailed guidelines for compliance with such accrediting agencies. The associated training program attached to this policy will also enhance general knowledge and assure the ethical conduct of all aspects of our animal research program.

### PROF. ABDULSALAM A. AL SULAIMAN

Vice President for Graduate Studies and Scientific Research



### **Administrative Decisions:**

The main Committee for animal care in Scientific Research has been established as per the President's administrative decision No. 43216 dated: 5/6/1436H.





### Committee Chairman:

• Dean of Scientific Research.

### Committee Members:

- Prof. Abduqader Homeida (Science College)
- Dr. Badryah Al-Swaigh (Science College)
- Dr. Nora Al-Jaloud(Science College)
- Dr. Ayman Al-Arfaj (Saudi Aramco)
- Veterinarian. Hussain Al-Hawaj (CRMC)



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Appendix 3. NACLAR Guidelines on the Care and Use of Animals for Scientific Purposes (Singapore), 2004

Appendix 4. Excerpt from NACLAR Guidelines for Institutional Animal Care and Use Committee, Chapter 2: Oversight of the Animal Care and Use Program

Appendix 5. NACLAR Guidelines for the Institutional Care and Use Committee, Chapter 3.2.11-13

Appendix 6. Excerpt from the AVMA Guidelines for Euthanasia of Animals, 2013 Edition, Pages 40 (Rodents) & 50-51 (Rabbits) Appendix 7. Excerpt from NACLAR The Guiding Principles for the Care and Use of Animals for Scientific Purposes, Appendix II: "Standards for Housing and Environmental Conditions" Appendix 8. Excerpt from NACLAR The Guiding Principles for the Care and Use of Animals for Scientific Purposes, Chapter 8, pages 29-43

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# Section I UOD Policy Governing Care and Use of Animals in Research

### Article 1. Introduction

The University of Dammam (UOD) is committed to the ethical care, welfare and use of all living creatures used in research at UOD. As stated in UOD's Standing Committee for Research Ethics on Living Creatures (SCRELC) Manual (Appendix 1), it also is committed to:

- Restricting animal use in research to circumstances when the objectives of the research otherwise cannot be realized;
- Reduction of the number of animals used in protocols to the minimum required to achieve the aims of the research project; and,
- Refinement of research protocols to minimize pain and stress in animals used in research.

With these points in mind, this policy and associated guidelines have been developed and implemented to provide the framework, within which, research using animals at UOD is conducted in a manner that is compliant with regulatory law and consistent with high standards of research ethics related to the welfare and use of animals in the conduct of such research.



### Article 2. Scope of Policy

### The scope of this policy covers:

- i. All aspects related to the acquisition, housing, care and use, and disposal of animals in the conduct of research at UOD; and,
- ii. Evaluation of reported specific concerns regarding the care for and/or use of animals research.

### Article 3. Policy Guidelines

The SCRELC Manuel, Article 33 (33.1 – 33.23) (Appendix 1) provides the overarching guidelines within which this policy is constructed. Section 2-4 of this Policy and the Center for Research and Medical Consultation (CRMC) Manual of Laboratory Animal Services (Appendix 2) provide the specific regulations, guidelines, operational procedures and training programs that facilitate our assurance of the ethical treatment of animals in the conduct of research at UOD.

### Article 4. Definitions

Definitions of the following terms are shown below to assure clarity of the meaning of terms within the context of this Policy.

4.1. AAALC means Association for Assessment and Accreditation of Laboratory Animal Care, International



- 4.2. *ARENA* means American Research Ethics National Association
- 4.3. *AVME* means American Veterinary Medical Panel on Euthanasia
- 4.4. *CRMC* means Center for Research and Medical Consultations
- 4.5. *Euthanasia* means the act of inducing humane death in an animal
- 4.6. *FELASA* means Federation of European Laboratory Animal Science Associations
- 4.7. *IACUC* means Institutional Animal Care and Use Committee
- 4.8. *Investigator* means a person who proposes or has approval to conduct a research project involving the use of animals
- 4.9. *MORRE* means Monitoring Office for Research and Research Ethics
- 4.10. NACLAR means National Advisory Committee for Laboratory Animal Research (Singapore)
- 4.11. OLAW means Office of Laboratory Animal Welfare



- 4.12. Research IRB or RIRB means Research Institutional Review Board. The SCRELC serves as this IRB for UOD
- 4.13. *SCRELC* means Standing Committee for Research Ethics on Living Creaturesat UOD
- 4. 14. *Staff* means all persons involved in the housing, feeding and general care of the animals or who otherwise assists Investigators
- 4.15. UOD means the University of Dammam

### Article 5. Acknowledgements

We wish to acknowledge our review of and the guidance received from the following publications in the creation of this Policy:

AAALAC: Guide for the Care and Use of Laboratory Animals (NRC 2011), Academics Press.

ARENA & OLAW Institutional Animal and Use Committee Handbook

NACLAR *Guidelines on the Care and Use of Animals for Scientific Purposes* (Singapore), 2004

Office of Laboratory Animal Welfare – Public Health Service Policy on Humane Care and Use of Laboratory Animals, NIH, USA

VAMA Guidelines for the Euthanasia of Animals: 2013 Edition,



### ISBN 978-1-882691-210-0

Each of these reference publications are available in the administrative office of the Animal Facility.

# Section II Guidelines for Institutional Animal Care and Use Committee(IACUC)

# Article 1. The Institutional Animal Care & Use Committee (IACUC)

1.1. The IACUC is delegated the responsibility from the Research IRB (RIRB) to oversee all operations related to the care and use of animals for research at UOD. It will report to the RIRB and recommend changes to the policy, regulations, guidelines & procedures as necessary to assure maintenance of high standards and performance in the ethical care and use of animals in research at UOD. The ARENA & OLAW Institutional Animal and Use Committee Handbook is kept in the Administrative offices of the Animal Facility as a reference available for all IACUC members.

### 1.2. Duties and Functions

### The duties and functions of the IACUC are:

- i. Review all research proposals involving use of animals and recommend actions to the RIRB
- ii. Oversee periodic inspections of the animal facilities



- iii. Perform annual reviews and recommend any needed modifications to the RIRB of all policies, rules, regulations, guidelines and procedures related to the care and use of animals
- iv. Investigate any and all legitimate complaints related to the care and use animals in research at UOD
- v. Oversee semi-annual reviews of approved projects to: assure investigator compliance with all policies and regulations related to use of animals; and, to make all findings and recommendations for action to the RIRB

### 1.3. Authority of the IACUC

The IACUC acts as an advisory committee to the RIRB in all matters other than recommendation for disapproval of a research proposal based on animal welfare and use concerns. In this instance, the IACUC will provide the specific reasons for disapproval to the RIRB but the RIRB cannot veto the decision of the IACUC and proceed withapproval of the project.

The investigator may make subsequent revisions to the proposal and ask for reconsideration by the IACUC at its next cycle of proposal reviews. In no instance, however, can the investigator request approval from the RIRB in conflict with a disapproval decision by the IACUC.

### 1.4. Appointment of IACUC Members

The RIRB Chair, in consultation with the RIRB members, has the authority to appoint members to the IACUC.

### 1.5. IACUC Membership and Qualifications



- 1.5.1. The IACUC will consist of no less than five (5 members), including its Chair.
- 1.5.1. At least one separate member of the IACUC must represent the following membership qualifications:
- i. A veterinarian experienced or trained in laboratory animal research with animal species being used for research at UOD. This individual can be the lead Veterinarian of the Animal Facility.
- ii. A scientist experienced with use of animals in research.
- iii. An individual representing a community who has no affiliation with UOD. This includes members of their immediate family.
- iv. An individual whose primary role and interests relate to ethical issues, e.g. lawyer, clergy, ethicist.

Note: A given member may have more than one of the above qualifications but each qualification must be represented by a separate person

- 1.5.2. No more than two members of a single department or unit of any college or center of UOD can serve on the IACUC at the same time.
- 1.5.3. No member of the IACUC can simultaneously serve on the RIRB.



- 1.5.4. The lead Veterinarian engaged with the Animal Facility shall be appointed, ex-officio, to the IACUC.
- 1.5.5. No individual serving in an administrative leadership position over any segment of the CRMC or the Animal Facilities may serve as the IACUC Chair due to the potential for, or the appearance of, a conflict of interest. This includes the lead Veterinarian noted in 1.5.4.
- 1.5.6. Secretarial duties for the IACUC will be performed by a non-member staff person appointed by the CRMC Chair. Such secretarial duties will consist of maintaining minutes of all committee meetings and records of all decisions by the IACUC relating to research proposals and other actions of the committee
- 1.5.7. Members of the IACUC will serve three (3) year appointment terms.

Members can be considered for reappointment to subsequent terms by the RIRB Chair.

### 1.6. Conflict of Interest Concerns

1.6.1. The investigator requesting IACUC approval of his/her research proposal may request that a specific member be excused from voting on their project if he/she believes a conflict of interest exists by the identified IACUC member.

In such a circumstance, the IACUC Chair will receive the request in writing and, following due diligence, determine if the request is justified. In such circumstance, the chair will



err on prevention of even the appearance of conflict of interest by the committee.

### 1.7. Quorum

- 1.7.1. A quorum of members must be present at a convened meeting of the IACUC for any action to be taken by the committee. A quorum is defined as more than 50% of the appointed IACUC members.
- 1.7.2. In a circumstance that a member has been excused from deliberation due to a conflict of interest, the remaining voting members must still represent greater than 50% of the total IACUC membership
- 1.7.3. Abstention from voting by a member on a specific action reduces the quorum of members present for that action by the committee and prevents such a vote if such a quorum is then not present for that action.
- 1.8. All actions taken by the IACUC, including facility reviews by the committee, actions taken regarding recommendations on proposed research projects, and other actions taken involving the care and use of animals at the Institution will be formally transmitted in writing to the RIRB in a timely manner.
- 1.9. Additional Manpower for Support of IACUC



1.9.1.As the volume and variety of animal resources utilized in research at UOD expands, the IACUC may need additional manpower to support their mission.

The IACUC will review annually their obligations for oversight of the program for use of animals in research and determine if additional staff is required for the discharge of its duties. Based on these reviews, the IACUC will make recommendations to the RIRB for varieties and size of additional staff needed to appropriately discharge their responsibilities.

The RIRB will evaluate such recommendations and provide needed support personnel as necessary.

### 1.9.2. Ad hoc Consultants

The IACUC may from time-to-time identify need for external consultants to advise the committee regarding matters pertaining to the use and care of animals in research. Based on such needs, the RIRB will provide financial support for the IACUC to obtain such ad hoc consultations.

### 1.10. Training of IACUC Members

- 1.10.1. At least fifty percent (50%) of the IACUC members must have undergone formal training in IACUC work. Recommended sources of such training include the ARENA IACUC 101 Workshop. References for such recommended sources will be maintained by the IACUC.
- 1.10.2. On appointment, new IACUC members must participate in the course on "Responsible Care and Use of Laboratory



Animals" as described in Section IV – Training Guidelines , if necessary to satisfy the requirements stated in 1.10.1. above.

### Article 2. Oversight of the Animal Care and Use Program

2.1. The IACUC must review all programs involving the use of animals in the Institution every six months and the facilities housing animals and research facilities in which animals are used on an annual basis using both this Policy & Guidelines for the Care and Use of Animals in Researchand the NACLAR *Guidelines*on the Care and Use of Animals for Scientific Purposes (Appendix 3) as reference sources to guidethese evaluations.

### 2.2. Conduct of Program and Facility Evaluations

The Institution has adopted Chapter 2 of the NACLAR *Guidelines* for Institutional Animal Care and Use Committee as the review guide with which to conduct these program and facility evaluations. This chapter has been excerpted verbatim and is provided as Appendix 4. The IACUCwill use this guide, as appropriate, in context to the size and variety of animal species being cared for and used in research at UOD. These review guidelines cover the following areas of importance:

- 2.3 Facility Review
- 2.4 Staffing and Scheduling the Facility Inspections
- 2.5 Performing Inspections
- 2.6 Use of AAALAC Programs to conduct Evaluations
- 2.7 Documentation



- 2.8 Animal Environment, Housing and Management
- 2.9 The Use of Microbiological Agents in Research on Animal Models
- 2.10 Emergency, Weekend and Holiday Care
- 2.11 Behavioral Management for Laboratory Animals
- 2.12 Role of the Veterinarian
- 2.13 Occupational Safety and Health
- 2.14 Personnel Training and Education
- 2.15 Emergency Preparedness
- 2.16 Disaster Planning

# Article 3. Reviews and Approval of Proposals Using Animals

The IACUC must review and approve all research projects involving the use of animals and provide this approval to the RIRB prior to the RIRB taking any action on submitted research proposals. IACUC rejection of such research proposals using animals cannot be reversed by the RIRB.

- 3.1. Primary Obligation of IACUC review
- 3.1.1.The primary role of the IACUC is to assure that research at UOD is conducted in compliance with all applicable laws, regulation, guidelines and policies relevant to use and care of animals in research; and, that the animals are managed in an ethical manner consistent with the research subject's species in relation to the justified research goals
- 3.1.2. The IACUC must assure itself that the goals of the proposed research could not be achieved: without the use of



animals; with a smaller number of animals; or, a lower species of animal (e.g. invertebrate versus vertebrate).

3.1.3. The IACUC is obligated to the engagement of an expert consultant in their review of a research proposal if such expertise is not present in the IACUC members themselves. Such consultants should be compensated for their review. The consultant may not vote on proposed actions by the committee.

### 3.2. IACUC Review Procedure

- 3.2.1.The IACUC chair will assign a member the responsibility of primary reviewer of each proposal. This assignment will be based on the presence of adequate expertise on the part of the member. If expertise does not exist in the IACUC membership, the Chair may assign primary reviewer status to an engaged expert consultant.
- 3.2.2. The primary reviewer will lead discussion of the project at the next scheduled meeting of the full committee. Following deliberation, the committee will vote in one of three ways:
- 1. A vote for approval
- 2. A vote for disapproval
- 3. A vote for deferral to acquire additional information or appropriate corrections of minor issues with the proposal. Following resubmission of the revised proposal, the committee may vote for approval or disapproval.



- 3.2.3. During the deliberative phase of the committee review, the investigator may be requested to be present to respond to unanswered questions or to provide additional insight into portions of the proposal. When asked to participate, the investigator is removed from the meeting prior to final discussion and vote on the proposal.
- 3.2.3. Committee actions on proposed research requires a quorum present and voting on the proposal (see Section 1.7.).
- 3.2.4. Committee minutes must be taken to record committee salient aspects of discussion; votes by the committee; and, reasons for disapproval of the proposed protocols.
- 3.2.5. Investigators may resubmit proposals with explanation and correction of recorded deficiencies.

### 3.2.6. Approval

Once the IACUC decision has been made, its action is forwarded to the RIRB Chair. The investigator should be reminded that ICUC approval is but one step in the approval process and that other specific approvals may be required before the RIRB provides its final decision.

### 3.2.7. Disapproval

Should the IACUC vote for disapproval of the research proposal; the IACUC chair will provide a written justification for such action to the RIRB Chair. In this circumstance, the



RIRB can take no further action on the proposal. The investigator may address the identified major issues related to the care and use of animals in research; and, pursue subsequent resubmission of the proposal for reconsideration by the IACUC.

- 3.2.8. The investigator should be encouraged to seek, and the IACUC should welcome the opportunity to provide advice and preliminary review of protocols under development. Not only does this diminish unnecessary steps in formal review process but it can also provide an opportunity to educate the investigator regarding the proper care for and use of animals in research.
- 3.2.9 Significant changes that are made to IACUC approved projects must receive "re-approval" from the IACUC before the revised project can be activated.

  Examples of significant changes include:
- a) Modification of the objectives, or end-points of the study;
- b) Significant modifications to the steps in the study, e.g. changing non-survival surgery to survival surgery;
- c) Significant increases in the stress and pain induced by the study;
- d) Changes in investigator or investigator's personnel engaged in managing the animals during the study;
- e) Change in anesthetic agents, or method used for euthanasia; and,
- f) Insertion of additional procedures into the study protocol.



The above examples are not meant to be exhaustive but should alert the investigator to the varieties of changes that require IACUC re-approval.

### 3.3 Protocol Review Criteria

- 3.3.1. The Investigator should include a section in his proposal addressing the specific questions shown below:
- 1. Can a non-animal model be used for the investigation?
- 2. Can the number of animals be reduced?
- 3. Can refinement of the research protocol lead to a reduction or elimination of pain and distress in the animals

The IACUC must review the protocol and the answers to the above questions to verify that such modifications are not possible. One of the most frequent errors in performing animal experimentation is the inaccurate estimation of the population of animals needed for the experiment.

Pilot studies frequently will require significantly fewer animals than a definitive experiment. The investigator should provide statistical support for the number of animals planned for the research.

### 3.3.2. Pain management

a. The IACUC should closely examine the protocol to determine if pain or significant stress to the animal is caused by the experiment. If such pain or distress cannot be removed, the committee must be satisfied that adequate management of pain is being provided. If stress is



unavoidable, consideration of pharmacological intervention should be considered. When the research protocol creates unavoidable pain or stress that cannot be managed due to the interference of pain management with the scientific validity of the experiment, the IACUC must determine if the scientific value of the research is sufficiently important and that no other methodof study is feasible. In such circumstances, the IAUC should explore any changes in the pain creating protocol that might reduce the period of suffering.

- b. The IACUC must evaluate the research protocol to determine if appropriate sedation, analgesia, and anesthesia is planned and determine if such pain control is to be given in a timely manner.
- c. The IACUC must confirm that the staff and investigators caring for the research animals understand and are alert to recognize signs of unmanaged or undermanaged pain and distress and are trained in delivery of appropriate pain management. A schedule of pain and distress symptoms are provided in the NACLARGuidelines for Institutional Animal Care and Use Committee, Chapter 3, article 3.2.11-13 (Appendix 5).

### 3.3.3. Humane endpoints

When endpoints of the experiment include death of the animal, the IACUC should inquire, if the experimental design will allow it, to consider foreshortening such a final endpoint such as using early signs of imminent death(e.g. diminishment of limb motor ability, somnolence, not eating or drinking water,



etc.). In this way, the animal can be euthanized earlier and interrupt the continued terminal spiral.

### 3.3.4.Euthanasia

Options for approved forms of euthanasia are species specific. Currently, only rodents and rabbits are used in research UOD. Appendix 6 is an excerpt from the "AVMA Guidelines for the Euthanasia of Animals: 2013 Edition" that describes acceptable methods of euthanasia for rodents (page 48) and for rabbits (pages 50-51).

### 3.4 Role of IACUC member Veterinarian

The Veterinarian IACUC member provides a critical role in the review of research protocols. His/her knowledge of medication dosages and mechanisms to identify pain and stress in research animals is important to the assessment of research protocols and to the proper conduct of the project. If the IACUC member veterinarian is not the lead Animal Facility veterinarian, the IACUC member veterinarian should liberally interact with the lead Animal Facility veterinarian to resolve questions pertaining to such care of the research animals.

### 3.5. Review of Personnel Qualifications

The IACUC should develop, in consultation with its member veterinarian, the appropriate qualifications and training of all individuals having responsibilities for care of animals or performance of interventions, including surgical



procedures, on animals used in any proposed protocol.

This includes qualifications of the investigator, research technicians, animal husbandry personnel and veterinarian and veterinary technicians.

### 3.6. Veterinarian Review and Consultation

3.6.1. The IACUC member veterinarian must have experience and training in the care and use of the animal species used in research at UOD. The veterinarian member should interact with the investigator and provide insight to other committee members on:

- 1. Selection of the species to be used for particular protocols;
  - 2. Appropriate management of potential pain and distress in the research animal;
  - 3. Protocols involving surgery, either minor or major;
  - 4. Selection of humane endpoints and euthanasia of the animals; and,
  - 5. Results of follow-up visits to the animal facility and evaluations of the wellbeing of the animals.

Additional examples of other responsibilities and roles served by the member veterinarian are provided the "NACLAR Guidelines for Institutional Animal Care and Use Committee", Chapter 3, 3.4.8, page 106 (Appendix 3)

3.6.2. Information regarding review and other topics of consideration by the IACUC in review of protocols, including agricultural research, antibody production, breeding



colonies field studies, Hazardous materials, instructional use of animals, surgery, and transgenic animals, are found in the "NACLAR *Guidelines* for Institutional Animal Care and Use Committee", Chapter 3, 3.5, pages 107-127 (Appendix 3).

### 3.7. Monitoring of Approved Protocols

The IACUC monitors the conduct of approved protocols through establishing

processes to assure adherence to all standards for the care and use of animals of research. These procedures should include:

3.7.1. Review of an annual report provided by the head of the animal facility.

This report should include: evidence attesting to the proper acquisition of the research animals; tracking of the use of animals in the respective protocols; the results of periodic evaluations of animals to assure adherence to all protocols for the proper care and use of animals; and, assurance that allinvestigators are adhering to their approved protocols for conduct of their research.

# Article 4. Process for Evaluation of Animal Care and Use Concerns

4.1. The IACUC will work closely with the MORRE to assure that all concerns, either written or verbal, registered by any individual, group or entity are received and evaluated to the extent warranted. A system, including a "Hot-line" service to



receive anonymous concerns, should be developed to encourage reporting by any concerned party of any such concerns. Investigation of such concerns will be handled confidentially and through a process that mimics the sequential processes undertaken by the Research Integrity Officer (RIO). These stepsare:

- 1. An initial evaluation by the IACC Chair to determine if a preliminary Inquiry phase is warranted;
- 2. A preliminary Inquiry phase by an appointed sub-set of the IACC membership to determine if a full investigation is appropriate; and ,
- 3. A formal Investigation by an appointed Investigation Committee for any concern that appears, on preliminary inquiry to have merit to warrant a full investigation.
- 4. Outcome of a preliminary inquiry and the Investigation phase will be reported to the RIRB Chair.
- 5. Any conclusion of an Investigation warranting action will be recommended to the RIRB Chair for his/her deliberation and action.
- 6. Any active protocol using animals related to the concern will be suspended until conclusion of the Investigation phase and actions by the RIRB Chair
- 4.2. In addition to specific concerns registered regarding the care and use of animals at UOD, the IACUC will be alert to and evaluate any circumstances surrounding use of animals in research that are brought forward in public venues to assure that such concerns are being managed ethically within the UOD Animal Facility and in the conduct of all research protocols using animals at UOD.



### Article 5. Records and Communications

- 5.1. The IACUC will maintain written records of all actions taken by the committee. Including the following:
- 1. Minutes of all meetings of the IACUC
- 2. All correspondence to the RIRB Chair
- 3. All Protocols reviewed, whether approved or not
- 4. All Annual reviews of the Animal Facility conducted by the IACUC
- 5. The Annual Report submitted by the head of the Animal Facility
- 6. All investigations into concerns related to the use and care of animals in research
- 7. Any other ad hoc deliberations by the IACUC
- 8. All policies, procedures and guidelines applicable to the care and use of animals in researchSuch material will be maintained in a secure, restricted location for at least seven (7) years, if not in perpetuity (items # 1,2,4,5 &8).



# Section III Regulations & Guidelines for Care and Use of Animals

## Article 1. General Principles for Care and Use of Animals in Research

- 1.1. Although UOD is currently using only mice and rabbits in its animal research, it must be ready to adopt regulations & guidelines for care and use of other species in research based on appropriate needs of investigators in the future. When additional animals species are to be utilized, the staff and the IACUC must affirm that the proper knowledge of their care and use is present in the investigator, the Animal Facility Staff and the IACUC members prior to such expansion.
- 1.2. Having adopted the NACLAR *Guidelines*(Appendix 3) as the reference source from which much of theoversight and management of the care and use of animals in research is measured, the IACUC must assure that all relevant guidelines, requirements and processes embraced in the NACLAR *Guidelines* are followed by all engaged parties. This includes the Animal Facility Staff, the investigators and the IACUC itself. Other valuable resources for guidance in delivery of proper care for and use of animals for research are provided in the "Acknowledgements" following Section I of this Policy.
- 1.3. Proper selection and care of research animals should include the following:



- a) Assure that animals are required for the research, i.e. replacement of animals with other methods is not scientifically feasible:
- b) Assure that the number of animals to be used is the minimum necessary to achieve the aims of the investigation;
- c) The investigator should verify that the proposed species is the most appropriate for the contemplated research;
- d) The investigator must design the project to avoid or minimize stress and pain to the research animal;
- e) Procedures causing more than momentary discomfort or stress must be accompanied by appropriate analgesia or anesthesia;
- f) At any point in the conduct of the research protocol that ongoing severe pain becomes unmanageable, the experimental animal must be humanely euthanized;
- g) If pain and stress is unavoidable as a component of the project, it must be managed with analgesics or have an endpoint as early as possible to avoid ongoing pain or stress.
- h) Death as an end-point should be avoided whenever possible. If such an end-point is unavoidable, the investigator should take proper precautions to minimize stress and pain with proper analgesics or anesthetics.
- i) Proper attention should be paid to species specific needs for transportation, housing, feeding, handling, behavioral and biological needs



### Article 2. Animal Housing and Management

### 2.1. General Background and Guidelines

- 2.1.1. As referenced earlier, rodents and rabbits are the only non-human species used for scientific research at UOD at this point (2015). These guidelines, however, refer to all potential species that may be used at UOD into the future.
- 2.1.2. Animal housing and management must be in compliance with all accepted international standards and guidelines as reflected in the NACLAR *Guidelines* and the AAALAC. These reference guides are maintained in the Offices of the Animal Facilities. All IACUC members, veterinarians, Animal Facility staff and investigators should be well verses in these standards as they apply to the housing and management practices related to the care and use of animals in research.

### 2.2. Housing Facility

Provision of proper housing should be species specific, compliant with the above stated reference guidelines. Species-specific requirements for housing environments are provided in Appendix 7 (excerpted fromNACLAR Guiding Principles for the Care and Use of Animals for Scientific Purposes, *Appendix II*: "Standards for Housing and Environmental Conditions"). General parameters should entail the following:

### 2.2.1 Proper control of environmental factors including:



- i. Provision of species specific lighting, light cycles, temperature and humidity;
- ii. Exclusion of vermin contamination through proper pest control programs;
- iii. Limitation of contamination related to storage and delivery of food, water, bedding, and entry of people or other animals;
- iv. Periodic monitoring of the facility to assure that all areas are kept clean (using approved detergents, disinfectants and pesticides only), dry and operated to maintain a high level of hygiene;
- v. Contingency plans should be in place to manage emergencies such as loss of electrical power, heating, cooling and/or ventilation;
- vi. Restriction of unauthorized persons entry into sites housing animals to minimize the risk of disease contamination and to enhance animal wellbeing; and,
- vii. Cages should be routinely cleaned of waste to minimize noxious and potentially harmful waste gases (e.g. ammonia);
- 2.2.2. All housing facilities (i.e. pens, cages and other containers housing animals)

should be constructed to species-specific standards to ensure wellbeing of the respective animal species. Detailed parameters affecting animal wellbeing are provided in Appendix 3, "NACLAR *Guidelines*, Principles for the Care and Use of Animals for Scientific Purposes", Chapter 3, 3.5.1-2. Pages 10-11.

2.2.3.Cages for housing rodents should have solid floors unless a wire floor is required for the investigation. In such



circumstances, the rodents should only be housed in wire floors for brief periods of time.

- 2.2.4. The number of animals housed in a single cage, pen or container and the location of such units should be consistent with proper concern for population density and the associated acceptable social and environmental condition for respective species. When housing social animals, isolation of single animals should be minimized to instances required by the approved project to prevent "isolation stress".
- 2.2.5. Proper bedding and litter should be provided and changed as necessary to provide a clean, non-noxious housing environment.
- 2.2.6. Pregnant animals must be provided species appropriate "nesting" materials within their housing unit.

### 2.3. Food and Water

- 2.3.1. Food should be appropriate to the species, uncontaminated and nutritionally adequate to maintain normal growth in immature animals, stable weight in adults and sufficient for the needs of pregnant animals. When fed in groups, there should be adequate feeding sites to facilitate sufficient space for all contained animals in the unit.
- 2.3.2. Feeding trays should be monitored routinely to remove perishable foods unless such removal is inconsistent with the feeding habits of the species.



2.3.3. Fresh clean and uncontaminated drinking water should be constantly available and provided in durable containers that are easily cleaned.

## 2.4. Routine Animal Husbandry Procedures

Routine animal husbandry duties to maintain the animal's welfare, such as an nail clipping, etc., should be performed by appropriately trained staff using accepted practices.

## 2.5. Identification of Animals

All animals must be identifiable to maintain accurate accounting for research and monitoring purposes. Methods to achieve these ends include individual tattoo, neckband, tag, etc. Housing units must be labeled with project title, investigator name and an identifier of the specific investigative sub-group held within the housing unit (pen, cage, container, etc.). Such identification should be accomplished as soon as possible after animal arrival to the Animal Facility and should be done with the least stress or injury possible.

## 2.6. Disposal of Animal Carcasses and Waste

All animal carcasses and biological wastes must be disposed in accordance with all relevant KSA laws, rules, regulations and guidelines for disposal of biological and hazardous wastes.

## 2.7. Management of New Animal Arrivals



- 2.7.1.All new animal arrivals should be placed in quarantine, separate from existing animals until cleared by the Animal Facility veterinarian. Inspection of the new arrivals should include the following:
- i. Inspection of the health of the individual animals;
- ii. Review of the suppliers certificate stating what pathogens have been tested within the prior 6 months and their results; and,
- iii. The suitability of the respective animals for the proposed research.
- iv. The quarantine period should be adequate to allow acclimation of the new animals and provide for standard observation periods to exclude emerging illness.
- v. Animals that do not adapt to the environment or appear unhealthy should not be kept.

## Article 3. Animal Procurement and Transport

## 3.1. Animal Procurement

- 3.1.1. All animals obtained within the Kingdom must be provided from a licensed or otherwise legally permitted source.
- 3.1.2. All foreign sources of animals must be recognized by the exporting country that they are a legitimate exporting supplier of the species.

## 3.2. Transport of Animals



- 3.2.1.Recognizing that transport may provide extreme stress to the animal, adequate period of recovery and assimilation should be provided in the "quarantine" period for all new arrivals.
- 3.2.2. Internal transport within UOD and the Animal Facility should be done with appropriate consideration for minimizing of movement, noise, extremes of temperature, period without food or water and any other environmental factor that might lead to undue stress.

## **Article 4.Veterinary Care and Staff at Animal Facility**

- 4.1 Veterinary Staff-in-charge
- 4.1.1. The Lead veterinarian in charge of the Animal Facility reports to the Director of the CRMC as well as to the IACUC. He/she must have the appropriate experience and animal care qualifications to oversee management of all species maintained at the Animal Facility.
- 4.1.2. Responsibilities of the Lead Veterinarian include:
- i. Responsibility for the day-to-day oversight and care of the animals and supervision of the other Animal Facility Staff;
- ii. Acting as the primary liaison between investigators and the staff providing day-to-day care;



- iii. Assurance that all policies and procedures for care and use of animals are followed by staff and investigators;
- iv. Recommend changes to and development of enhancements to the Institutional Policy for Use and Care of Animals in Research;
- v. Assurance that there is reliable monitoring of the wellbeing of all animals by the staff and that general provisions of care defined in research protocols are appropriately provided by the staff;
- vi. Assurance that investigators are appropriately monitoring and providing protocol care for their research animals;
- vii. Assurance that all ill or injured animals are promptly treated and that any unexpected animal death is appropriately investigated, including, when warranted, performance of autopsies;
- viii. Assurance that all injuries, unexpected deaths, or other mishaps in the care and use of animals are recorded and reported to the IACUC;
- ix. Assurance that all units housing animals (e.g. pens, cages, containers, etc.) are maintained in compliance with the guidelines of this Policy;
- x. Performance of regular inspections of all components of the Animal Facility, including its housed animals, and



maintenance of records from such inspections and their results;

- xi. Performance of annual staff reviews and assessments;
- xii. Maintenance of all records related to animal purchases, transport, assignment to protocols, care, health status and ultimate status (e.g., unexpected death, euthanasia or otherspecify) of all animals;
- xiii. Assurance that investigators are immediately informed of any change in the status of their research animals;
- xiv. Assurance that all relevant records are available to the investigators and the IACUC; and,
- xv. All staff is appropriately trained and credentialed for their respective duties.
- xvi. Provision of a formal arrangements for provision of 24 hours per day & 7 days a week (24/7) "back-up" veterinarian care for the animals and consultative supervision of staff in his/her absence (e.g. during vacation, illness, travel, etc.)
- 4.2. Responsibilities of Animal Facility Staff
- 4.2.1. All staff should be well versed in the critical importance of and methods to maintain the wellbeing of the research animals.



- 4.2.2. All staff should be appropriately trained to ensure their knowledge of and performance of their assigned duties.
- 4.2.3. New Staff must participate in the Animal Care and Use Training program (Section IV)

## Article 5. Components of Veterinary Care

- 5.1. The lead veterinarian must assure that all standard needs for provision of routine and emergency veterinary care and consultative services is available on a "24/7" basisand that the associated facilities, personnel, equipment and services are in compliance with the "NACLAR *Guidelines* Principles for the Care and Use of Animals for Scientific Purposes", Chapter 8, pages 29-43 (Appendix 8).
- 5.2. Routine daily surveillance by the veterinarian and/or staff must be performed to: affirm animal wellbeing; prevent and control diseases in the animal population (e.g. vaccination, monitoring, quarantine, etc.); and, diagnose and treat illnesses or injuries.

## Article 6. Responsibility of Investigator

6.1. Research using animal models involves the use of living creatures for the betterment of humankind. It, thereby, entails the assumption of ethical standards, moral obligations



and professional responsibilities for the wellbeing of such living creatures by investigators engaging in such research.

These direct obligations and responsibilities assumed by the investigator must be embraced and discharged with commitment and adherence to all principles and established guidelines related to the care and use of animals in scientific research

6.2. Appendix 8 (NACLAR *Guidelines'* "Principles for the Care and Use of Animals for Scientific Purposes", Chapter 8, pages 29-43) provides the specific responsibilities, obligations and procedures that the investigator must assume and follow in his/her duty as the individual responsible for creation and conduct of the research protocol using animals. Each investigator must attest in writing that he/she has reviewed this appendix and fully commits to its articulated duties and responsibilities.

# 6.3. Investigator's Application for Use of Animals in Research Proposal

Investigators considering development and submission of a research protocol using animals must first contact the Animal House Facilities Director or Veterinarian and obtain a copy of the Prince Mohammed Center for Research and Consultation Studies "Laboratory Animal Services" (May 2014) manual (Appendix 2). This manual provides a brief review of all salient components of required knowledge and processes necessary to apply for use of animals in research.

Topics covered in this manual are:



- A. Information for users and Standard Operating Procedures for PMCRCS Animal House Facilities:
- B. Animal Care & Use Committee (ACUC)
- C. Application Procedure
- D. Application Format for Protocol Approval involving Laboratory Animal Use
- E. Procedural Flow chart for Obtaining Animals from CRMC AnimalFacilities; and,
- F. Annexures

The Investigator must attest to his/her review and familiarity with all contents of this manual.

# **Section IVTraining Guidelines**

## Article 1. Introduction

- 1.1. All UOD personnel engaged in the care and use of animals for research must have partaken in the educational and/or training course appropriate for their position and activity. Individuals included in this requirement are the:
- Animal Facility veterinarian
- Animal Facility staff
- Research Investigators & staff
- IACUC members
- Service personnel



Education and/or training courses for each category of engaged parties are provided in the following articles.

## Article 2. Animal Facility Veterinarian

2.1. The Lead Veterinarian must have experience with the care and use of animals in research and have been certified through approved courses in veterinary care of research animals. Certification of training though the FELASA Category D program (Appendix 9) is recognized as appropriate training.

# **Article 3.** Animal Facility Staff

#### 3.1. Animal Technical Staff

The Animal technical staff must be certified through a recognized training course for the care and use of animals in research. The FELASA Category A program (Appendix 10) is recognized as such a course.

## 3.2. Staff

Animal care staff must be certified through a recognized training course for the care of animals used in research. The FELASA Category C (Appendix 11) program is recognized as an approved course for staff working in the Animal Facility.



## Article 4. Researchers

4.1. Investigators must show evidence of knowledge and training in the care and use of animals for research prior to being granted approval of a research protocol application. The FELSA Category B (Appendix 12) program is an accepted course designed for education and training of investigators.

#### Article 5. IACUC Members

5.1. At least 50% of the IACUC members must have completed an approved course designed for IACUC members The ARENA IACUC 101 program (Appendix 13) is such an accepted course for IACUC members.

## Article 6. Service Personnel

- 6.1. Service personnel entering any area of the Animal Facility where animals are housed and areas used in research protocols should be accompanied with a member of the Animal Facility Staff to ensure that the welfare of the animals and associated equipment are not jeopardized.
- 6.2. No service personnel may enter the operational areas of the Animal Facility without prior approval by the Laboratory Director, Veterinarian or Technical Staff.



# Article 7. Handling Biohazards

- 7.1. Preliminary training should be arranged for all personnel handling bio hazardous material or where such personnel might be involved in biohazard-relatedwork. Examples of such biohazards include:
- a) Genetically modified organisms
- b) Radiation, including x-ray, isotopes, etc.
- c) Carcinogens, etc.

-END-

