IACUC SOP 00
TEXAS A&M UNIVERSITY-KINGSVILLE
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

(Revised: August 2016)

TAMUK Institutional Animal Care and Use Committee (IACUC)

Office of Research and Sponsored Programs (ORSP)

Standard Operating Procedure (SOP)
Texas A&M University-Kingsville (TAMUK) regards the use of animals in research and teaching to be an integral component of continued progress in science, education, and agriculture. TAMUK expects all of its animal facilities and programs to maintain the highest standards of animal care and use, and to be operated in accordance with applicable federal, state, and local laws, regulations, policies, and guidelines.

Authority
The Institutional Animal Care and Use Committees (IACUCs) derive their authority from the law. The Health Research Extension Act (HREA) of 1985 and the Animal Welfare Act of 1966 mandate the existence of IACUCs. The laws require the Chief Executive Officer (CEO) of an organization to appoint the IACUC, whose responsibilities are delineated in the law as well as federal policy and regulations. The Office of Laboratory Animal Welfare (OLAW) considers the CEO to be the highest operating official of the organization. The President of Texas A&M University – Kingsville delegates authority to the Institutional Official (IO) to appoint and remove individuals to and from the IACUC on an annual basis.

The Associate Vice President of Research and Dean of Graduate Studies shall serve as the IO. The IACUC reports to the IO. The Associate Vice President of Research and Dean of Graduate Studies, TAMUK's IO, is given the administrative and operational authority to commit institutional resources to ensure compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, Animal Welfare Regulations (AWR) and other requirements.

The IACUC's mandate to perform semiannual program evaluations as a means of overseeing the animal care and use program puts the IACUC in an advisory role to the IO. In its semiannual reports the IACUC advises the IO of the status of the Institution's compliance, establishes plans and schedules for correcting deficiencies necessary to either maintain or achieve compliance, and makes recommendation to the IO regarding any aspect of the Institution's animal program, facilities, or personnel training.

The IACUC's authority to review and approve protocols is independent of the IO, who may not overrule an IACUC decision to withhold approval of a protocol. If the IACUC approves a protocol, however, the Institution is not required or obligated to conduct the research activity. The Institution may also subject protocols to additional institutional review (e.g., department head, Biosafety committee, etc.).

IACUC SOP 01 - COMMITTEE MEMBERSHIP AND OVERSIGHT

(Revised: July 12, 2016)

As required by AWA 2.31, b2 and PHS policy IV, A, 3, b, the IACUC is composed of a chairperson, and at least two additional members, one of whom shall be a Doctor of Veterinary Medicine, and one of whom shall not be affiliated in any way with the facility, other than as a member of the IACUC. The IACUC may use consultants as necessary during review discussions. If the committee consists of more than three members, not more than three members shall be from the same administrative unit of the facility.

The PHS Policy and AWRs mandate the appointment of a veterinarian with direct or delegated program responsibility to the IACUC. The veterinarian with program responsibility (e.g., Attending Veterinarian) must have training or experience in laboratory animal science and medicine or in the care of the species being used.

Required categories of membership include:

- **Veterinarian:** The IO may appoint more than one veterinarian to the IACUC.

- **Chair:** The Chair is an appointed faculty member with research experience.

- **Nonaffiliated:** The nonaffiliated member(s) represent general community interests. Neither they, nor their immediate family, have an affiliation with TAMUK. These members have equal status (e.g., voting) to every other committee member and are provided the opportunity to participate in all aspects of IACUC functions.

- **Scientist:** PHS Policy requires that the IACUC include a practicing scientist experienced in research involving animals.

- **Nonscientist:** PHS Policy requires that the IACUC include a member whose primary concerns are in a nonscientific area. Examples include, but are not limited to, ethicist, lawyer, member of the clergy, librarian, etc.

The institution should consider persons with expertise in the disciplines involved in institutional research and teaching programs for service on the IACUC. In addition to the required categories of membership, it is suggested that individuals with expertise in specific areas pertinent to protocol review and program oversight be considered (e.g. statisticians, occupational health experts, information resource specialists, animal health technicians, and scientific research staff).

There is no requirement that any particular member or category of members be present at all IACUC meetings. The institution, however, must have a properly constituted IACUC in order for the IACUC to conduct valid official business.

Alternate members may be appointed to the IACUC as long as they are appointed by the IO. Alternates should receive training identical to the training provided to regular IACUC members.

Table A. Comparison of IACUC Membership Requirements

Table A. Comparison of IACUC Membership Requirements	USDA Regulations 9 CFR, 2.31 (a) (b)
• Appointed by the IO • Minimum of five members (requiring the following): o One Doctor of Veterinary Medicine with training or experience in laboratory animal science and medicine who has direct or delegated program authority and responsibility for activities involving animals at the institution. o One practicing scientist experienced in research involving animals. o One member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, clergy). o One member not affiliated in any way with the institution and not a member of the immediate family of a person who is affiliated with the institution. • The PHS Policy requires institutions to follow the *Guide*, which states that committee membership should include at least one public member to represent general community interests in proper care and use of animals, and that public members should not be laboratory animal users.	• Appointed by the IO • Minimum of three members: o At least one Doctor of Veterinary Medicine with training or experience in laboratory animal science and medicine, and who has direct or delegated program responsibility for activities involving animals at the institution. o One member not affiliated in any way with the institution and not a member of the immediate family of a person who is affiliated with the institution; person who represents the general community interests in the proper care and treatment of animals; and is not a laboratory animal user (USDA Policy 15) o Not more than three members from the same administrative unit of the institution.

SEMIANNUAL PROGRAM REVIEW AND FACILITY INSPECTIONS

(Revised: August 2016)

Semiannual Review
The IACUC reviews the program for humane care and use of animals at least twice annually, using the *Institutional Animal Care and Use Committee Guidebook* as the basis for evaluation. The IACUC also inspects all institutional animal facilities at least twice annually not to exceed 195 days between inspections.

Program Review
The animal care and use program review includes an evaluation of institutional policies and responsibilities (lines of authority and reporting channels), IACUC membership and functions, and IACUC recordkeeping and reporting procedures.

The IACUC will review at least twice annually, not to exceed 195 days between reviews, TAMUK's program for humane care and use of animals, using the Guide as a basis for evaluation.

The IACUC procedures for conducting semiannual program reviews are as follows:

The IACUC reviews TAMUK's animal care and use program using the OLAW Program review and facility inspection checklists, as found at: https://grants.nih.gov/grants/olaw/sampledoc/cheklist.htm . Each program area is evaluated and any deficiencies are categorized as minor or significant. No member is excluded from participating in any portion of the program review.

The semiannual program review is conducted at and voted on at a convened IACUC meeting. The results for the review must be signed by a majority of IACUC members. The report is submitted to the IO.

Facility Inspection
The facility inspections are a physical inspection of all buildings, rooms, areas, enclosures and vehicles that are used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. TAMUK, through the IACUC, is responsible for all animal-related research, testing, teaching, and production activities. The IACUC must have reasonable access to these areas for the purpose of verifying that activities involving animals are being conducted in accordance with the proposal approved by the IACUC.

The IACUC inspects, at least twice annually not to exceed 195 days between inspections, all of the TAMUK 's animal facilities using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

1. Semiannually the IACUC organizes the inspection schedule of the animal facilities located on campus. These inspections are conducted using the *Institutional Animal Care and Use Committee Guidebook*, the *PHS Policy on Humane Care*, the *Guide for the Care and Use of Agricultural Animals in Research and Teaching*, and *Use of Laboratory Animals*, as a basis for evaluation. Deficiencies are categorized as minor or significant. All IACUC members are invited, and encouraged, to attend the facility inspections. At a minimum, two (2) members are present for each inspection. Any member wanting to be present at an inspection may be accommodated, but cannot be part of the inspection team when a COI exists.
2. A responsible party (e.g., Principal Investigator, hereinafter referred to as PI) is notified, in writing, of any minor or significant deficiency identified in his/her laboratory, facility or designated space. Responsible parties are required to promptly provide a response to the deficiency notification with a description of how the deficiency has been corrected or to submit a written plan with a timeline outlining how the deficiency will be corrected.

3. Facility Inspection notes are compiled by the Research Compliance Team and prepared for IACUC review following the inspections at a convened IACUC meeting where the Chair requests any additional comments and/or minority views from all members present.

Categories to be inspected:
Areas of inspection may include, but are not limited to:

- Sanitation
- Food and water provisions
- Animal identification
- Waste disposal
- Animal health records
- Controlled and/or expired drugs
- Environmental conditions
- Occupational health and safety concerns
- Staff training
- Physical security requirements

Advance notification will be given to all supervisory personnel prior to semiannual facilities inspection.

Performing Inspections
Adherence to the following recommendations will assist the IACUC in performing inspections:

- The IACUC maintains an updated list of all facilities.
- All proposals submitted to the IACUC will specify locations where animal procedures will be performed.
- Apparent deficiencies will be discussed with the person in charge of the facility to ensure that the IACUC's perception of the situation is accurate.

Deficiency Correction Schedule
All deficiencies identified during the Facility Inspection and/or Program Review are designated by the IACUC as minor or significant. A significant deficiency is defined as a situation that is or may be a threat to animal health or safety.

AWAR §2.31(c)(3); PHS Policy IV, B, 3:

> A significant deficiency is one which in the judgement of the IACUC and the IO, is or may be a threat to the health or safety of the animal.

For both categories of deficiencies, a reasonable and specific plan and schedule with dates for correction must be included in the final report. All individuals to be involved in the corrections should be consulted to ensure that the plan is realistic. An individual will be identified at the meeting following the inspection to follow up and verify completion of deficiency correction.

Documentation
A written report of the semiannual program review and facility inspection is prepared. The report is signed by a majority of the IACUC.
The report will indicate whether or not any minority views were filed, and minority views will be included in the final document. A copy of the report is sent to the IO and is kept on file for a minimum of three years in the ORSP.

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Reporting Animal Welfare Concerns

(Revised: August 2016)

Procedures for Handling Reports of Animal Welfare Concerns

- Any report of an immediate threat to animal welfare will be addressed without delay.
- Any individual may report concerns to the IO, Office of Research & Sponsored Programs, IACUC Chair, Institutional Veterinarian, or any member of the IACUC.
- Any concern can be reported either verbally (in person or phone), in writing, or via web- or phone-based hot-line (”Ethics Point”). 1-888-501-3850. https://secure.ethicspoint.com/domain/media/en/gui/19681/index.html
- Notices are located in the animal facilities and on the Office of Research and Sponsored Programs web-site advising individuals how and where to report animal welfare concerns and stating that any individual who, in good faith, reports an animal welfare concern will be protected against reprisals.
- All reported concerns will be recorded and brought to the attention of the full IACUC.
- If necessary the IACUC Chair will convene a meeting to discuss, investigate, and address any reported concern.
- Reported concerns and all associated IACUC actions will be recorded within the IACUC meeting minutes.
- The Committee will report such actions to the IO and, as warranted, to OLAW. Reports to the IO may be either via meeting minutes, semiannual report of IACUC evaluations, or separate letter. Reports to OLAW will be in writing and through the IO. Initial reports to both the IO and OLAW may be made verbally.

Regulatory Authority
The Texas Whistleblower Act of 1989 protects public employees who make good faith reports of violations of law by their employer to an appropriate law enforcement authority. An employer may not suspend or terminate the employment of, or take other adverse personnel action against, a public employee who makes a report under the Act.

The USDA Animal Welfare Regulations provide protection against discrimination or other reprisals for reporting violations of the Animal Welfare Act (“whistleblower protection”). The regulations provide that, “No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulations or standards under the Act.” (9 CFR § 2.32(c)(4)).

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MONITORING OF APPROVED PROTOCOLS

(Revised: January 2017)

Continuing Reviews TAMUK IACUC protocols are active for three years. Some research projects will extend beyond this window, and ongoing research as interpreted by OLAW will require a *de novo* review, as specified in IV.C. of the PHS. The IACUC requires a Third Year Resubmission be submitted as a new protocol, using the most recent version of the application.

The three-year period begins on the actual date of IACUC approval; the IACUC may not administratively extend approval beyond the three years. Since protocol approval period cannot be extended, investigators must be cognizant of the protocol approval period. To aid investigators, the ORSP shall attempt to provide adequate warning of pending protocol expiration. It is the ultimate responsibility of the investigator to submit the third-year resubmission by the appropriate deadline date for a scheduled Full Committee Review (FCR) prior to protocol expiration.

In order to address the federal requirement that significant changes be reviewed by the IACUC (*The IACUC Handbook 3rd Edition*, 10.3), a new protocol submission is required for the following:

- Addition of survival surgeries
- Changes in the purpose or aim of the study
- Change of PI
- Need to repeat an experiment utilizing more animals (on a case by case basis)

Any other changes to the protocol will be submitted for review as an amendment to the approved protocol. See the SOP: IACUC Protocol Amendments.

Post-Approval Monitoring/Continuing Reviews
Each approved IACUC protocol will be subject to an Annual Continuing Review before the first and second anniversary of its initial approval date.

No later than 2 months prior to the anniversary of the IACUC protocol approval date, the ORSP will send the IACUC Continuing Review form to the PI of the approved protocol, asking for a progress report, if any adverse events have occurred, a record of animal use, if changes are planned, or to certify that the project is finished and may be closed. It is requested that the PI will fill this in, return it to ORSP within 7 business days, and if received less than 3 business days before the next meeting, it will go on the agenda for that meeting. If the time to the next meeting is more than 3 business days, the CR will be sent out for review via DMR to avoid delays should quorum not be met at the next meeting. The IACUC determines if this project still falls under its originally approved activities, or if an amendment or new protocol are required. CITI Training and OHP enrollment is re-verified during the Continuing Review. Should the PI not respond to the initial requests for their CR report, their Department Chair and Dean will be contacted as well. Should a PI not submit the initial form for review or revisions in time for approval, the protocol will be closed and a new one will be required before activities can be resumed.

Before the third anniversary of an approved IACUC protocol, an expiration notice will be sent by ORSP, notifying the PI that a new protocol is required to continue their activities if the project is ongoing.

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IACUC SOP 12
GUIDELINES FOR THE USE OF DRUGS AND CHEMICALS IN ANIMAL RESEARCH

These guidelines have been written to assist faculty, staff, and students in performing vertebrate animal procedures in a humane manner and complying with pertinent regulatory requirements. Under some circumstances deviations from these procedures may be indicated but such variances must be approved in advance by the IACUC.

Biomedical, animal, and wildlife research and teaching programs often require controlled substances for prevention of pain and/or distress. In order to promote the humane use of drugs and chemicals, both the NIH and the USDA have issued guidelines for investigators, and the IACUC is charged with ensuring compliance with these guidelines. In general, the use of drugs in animals falls into one of two usage categories: standard veterinary care or experimental use. These guidelines apply to both types of administration. This document provides an overview of requirements that must be met when using drugs and chemicals in laboratory and animal research. It is organized into six sections:

Requirements

1. **Current standards for the veterinary care of research animals state that pharmaceutical grade medications should be used for routine medical treatment.** Pharmaceutical grade drugs are tested for purity to reduce the possibility that they are contaminated with toxic compounds that may harm an animal. Examples of routine veterinary procedures that involve the use of drugs include surgery, treatment of infection, administration of pain control, and euthanasia. Drugs used for these procedures (including anesthetics such as ketamine, pentobarbital, or isoflurane; analgesics such as carprofen or buprenorphine; antibiotics; supportive fluids; parenteral nutrients; etc.) used either as part of the IACUC-approved study or a veterinarian-approved treatment plan should be obtained from a veterinary supplier or from a pharmaceutical supplier licensed by the FDA, if it is available from such sources. Typically, drugs obtained this way will be in a form that is packaged, labeled, and licensed for either animal or human clinical use.

2. **Chemicals and compounds administered to research animals for experimental objectives should also be of the highest purity possible.** There are two categories of drugs used for experimental purposes: already in clinical use or not approved for clinical use. If the drug is currently approved for clinical use (either in human or animals), then the principle investigator should determine whether a formulation of the drug is available that is suitable for the experiment in question. Most drugs are formulated to contain excipients that are safe for clinical use, but may interfere with experimental objectives. If the excipients do not confound the study, then the drug should be obtained from a veterinary supplier or from a pharmaceutical supplier licensed by the FDA. If excipients interfere with the experimental objectives or if the chemical is not approved for clinical use, the investigator is allowed to formulate the drug or chemical provided that purity and stability of the drug is maintained. In this case, the investigator must submit a protocol that describes and justifies the proposed use of the drug or chemical formulation, and the IACUC must review and approve the protocol before experiments are carried out. For example, the pharmaceutical version of a drug marketed for IV injection may not be formulated with an appropriate concentration or vehicle for administration via an intracerebral cannula or osmotic mini-pump. Furthermore, controlled scientific studies may require a control group dosed with the vehicle only, and the vehicle may not be readily available. Finally, some studies will use novel chemicals or mixtures of chemicals either synthesized or isolated from natural sources. These chemicals should be of the highest purity attainable (either from commercial sources or from laboratory procedures during their preparation) and formulated in an appropriate manner for a specific route of administration. When new drug or chemical formulations are proposed, the IACUC may consider factors such as the grade, purity, sterility, pH, pyrogenicity, osmolality,

stability, site and route of administration, formulation, compatibility, and the pharmacokinetics of the chemical or substance to be administered. Principle Investigators are encouraged to contact a veterinarian regarding the preparation of the protocol before submission to the IACUC, but in some instances a pharmacologist or toxicologist consult may be warranted.

3. **Expired drugs or fluids must not be administered to research animals without explicit IACUC approval.** All expired drugs, including anesthetics and analgesics, must be segregated and clearly marked "EXPIRED" on or before their date of expiration. If the PI feels that any use of expired materials is justified (e.g., used of as part of a brief non-survival procedure) this must be specifically submitted for IACUC approval in advance.

4. **Drugs without expiration dates should be dated upon receipt**. The Principle Investigator should determine the stability of the drug to come up with a reasonable shelf-life. This is commonly obtained from the manufacturer, and for most stable organic compounds the shelf-life is up to three years. If stability is unknown, the drug should not be used beyond one year. Dates must be tracked and unused drugs must be segregated and clearly marked "EXPIRED" after the labeled shelf-life has expired.

5. **All dilutions and mixtures of drugs removed from the manufacturer's primary packaging are to be discarded after one month from the date of preparation unless the manufacturer specifies a longer dilution shelf-life.** Drugs and chemicals could degrade after dissolution or dilution and they may be more prone to bacterial contamination. For these reasons, even if it is earlier than the manufacturer's drug expiration date, all dilutions or mixtures made from a drug must be discarded after one month. The IACUC will consider deviations from this policy if the Principle Investigator submits a compelling justification explaining why the stability and purity of the compound is expected to be maintained longer than one month.

6. **Controlled Substances**:

    a. Controlled substances are classified into five categories according to their medical use and potential for abuse. For example, Schedule I substances are categorized as having no medical value and having the highest potential for abuse. Whereas Schedule V is categorized as having the least potential for abuse.
    b. Every person conducting **research activities** with a Schedule I controlled substance is required to register with the Drug Enforcement Agency (DEA) utilizing Form-225 Application for Registration. Additionally, the applicant shall submit three copies of a Notice of Claimed Investigational Exemption for a New Drug (IND) together with a statement of the security provisions (as proscribed in paragraph (a)(2)(vi) of this section for a research protocol) to, and have such submission approved by, the Food and Drug Administration as required in 21 U.S.C. 355(i) and Sec. 130.3 of this title.
    c. Every person conducting **institutional activities** with Schedule II – V substances is required to register with the Drug Enforcement Agency (DEA) utilizing Form-224 New Application for Registration (use applies to both research and institutional activities). Registration renewal is required annually with university employees are exempt from the registration fee (21 CFR §1301.21).
    d. The registrant is responsible for managing controlled substances in accordance with requirements of the regulations including inventory, record keeping, and security provisions. Agents of the registrant may engage in approved activities under the direction of the registrant. The registrant is required to screen those employees (i.e., Graduate Assistants) prior to authorization and annually thereafter until no further access is required. As part of the screening process, a questionnaire including the following

questions (21 CFR §1301.90) must be completed for each non-practitioner having access to and authorized to handle DEA controlled substances:

i. ***Within the past five years, have you been convicted of a felony, or within the past two years, of any misdemeanor or are you presently formally charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses or military convictions, except by general court-martial.) If the answer is yes, furnish details of conviction, offense, location, date and sentence.***

ii. ***In the past three years, have you ever knowingly used any narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician? If the answer is yes, furnish details***.

e. To ensure accountability, a complete and accurate continuing record (e.g., real-time inventory) is required for each controlled substance and must be maintained on a current basis. Continuing records should be kept for 30 years (TAMUS Records Retention Schedule) after the substance is spent. Inventories and records of Schedules I and II shall be kept separately from all other records maintained by the registrant. Similarly, inventories and records of controlled substances in Schedules III, IV, and V must be maintained separately from all other forms maintained or in a form readily retrievable from the ordinary business records of the registrant. It should include:

i. Date of Receipt
ii. Name of Substance
iii. Each finished form of the substance (e.g., 10mg tablet or 10mg concentration/ml)
iv. Number of units or volume of each finished form in each container
v. Number of containers for each finished form (e.g., six 3ml vials)
vi. *Date of dispensing, units or volume dispensed, units or volume remaining in container, name or initials of the dispensing individual*
vii. *If substance is acquired from, or distributed to another registrant, their name, address, and DEA registration number must be recorded along with the date and number of units acquired or distributed*
viii. *If disposal is required use DEA Form 41*

f. After initial inventories of controlled substances for Schedules I – V are taken, the registrant shall take new Biennial inventories or as required by IACUC of all controlled substances on-hand. Each inventory shall include:

i. Item number
ii. Noun Name of controlled substance
iii. Common name of controlled substance
iv. Finished form concentration
v. Number of units or volume of each finished form in each container
vi. Quantity of containers
vii. Total volume
viii. *Lot number*
ix. *Expiration date*
x. *Disposition date*

g. Damaged, defective, expired, or impure substances awaiting disposal must be inventoried stating why the substance is being maintained.

h. Expired controlled substances must be kept separate from non-expired drugs, but under the required secure storage conditions in accordance with the Controlled Substances Act (21 CFR 130), labeled as "EXPIRED" and be disposed of by approved means in compliance with the Controlled Substances Act. If you are uncertain whether the substance you have is controlled, please visit DEA Controlled Substance List. (Examples: Ketamine, Buprenorphine, Pentobarbital).

7. **Controlled Substances Disposal**: Enterprise Risk Management and the University Police Department (UPD) coordinate all controlled substances disposals utilizing local law enforcement jurisdictions. These events are free of charge, but disposal requests are required through IACUC. Additional information about the disposal and copies of the transfer form (DEA Form 41) can be found on the DEA Webpage.
8. **Record Review:** Inventories (biennial and real-time continuing records) and other records including copy of certificate of registration, purchase orders, copy of DEA Form 222 (if applicable), loss records, and non-practitioner screening questionnaires must be kept at the registered location and made available to appropriate authorities for review.

Who to Contact For More Information:

Office of Research and Sponsored Programs, Research Compliance: 361-593-2677
Attending Veterinarian: 361-593-3948
Enterprise Risk Management: 361-593-2237
University Police Department: 361-593-2611

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FOOD AND FLUID RESTRICTION

(Approved: October 2015)

When experimental situations require food or fluid restriction, at least minimal quantities of food and fluid must be available to provide for development of young animals and to maintain long-term well-being of all animals. Restriction for research purposes must be scientifically justified and approved by the IACUC. Experimental procedures utilizing food or water restriction must include a program for daily monitoring of physiologic and behavioral indices, including criteria (such as weight loss or state of hydration) for temporary or permanent removal of an animal from the experimental protocol.

Precautions

Precautions that should be used in cases of fluid restriction to avoid acute or chronic dehydration include daily recording of fluid intake and recording of body weight at least once a week or more often, as might be needed for small animals. Special attention must be given to ensure that animals consume a suitably balanced diet, because food consumption might decrease with fluid restriction. The least restriction that will achieve the scientific objective should be used. In the case of conditioned-response research protocols, use of a highly preferred food or fluid as positive reinforcement, instead of restriction, is recommended.

Guidelines

- Restriction must be scientifically justified.
- The least restriction that will achieve the scientific objective should be used.
- Criteria must be defined (such as weight loss or state of hydration) for temporary or permanent removal of an animal from the experimental protocol.
- A monitoring program must be established which includes regular observation of the animals (as outlined in the protocol).
- A daily log sheet must be maintained, and kept with the animals, with the following information:
    - Record of food/water schedule
    - Health status of the animals
    - Any adverse events
    - Body weight should be recorded at least weekly

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PHYSICAL RESTRAINT

(Approved: October 2015)

Physical Restraint

Physical restraint is the use of manual or mechanical means to limit some or all of an animal's normal movement for the purpose of examination, sample collection, drug administration, therapy, or experimental manipulation. Typically, animals are restrained only for a few minutes. Prolonged restraint is to be avoided, unless it is essential for achieving research objectives and is specifically approved by the IACUC.

Restraint Devices

Restraint devices should be suitable in size, design, and operation to minimize discomfort, pain, distress, and the potential for injury to the animal and/or personnel. When appropriate for the species, animals should be acclimated and trained to cooperate with the personnel and the device/procedures, and/or to remain immobile for brief periods.

Evaluation of Protocols

In addition to scientific rationale and justification, the IACUC will consider the following in the review of protocols involving animal restraint:

- Restraint devices should not be considered a normal method of housing; the use of such devices must be fully justified by the Principal Investigator (PI), including a clear explanation of the purpose and duration of the restraint.
- Restraint devices are not to be used simply as a convenience in handling or managing animals.
- Whether alternatives to restraint have been discussed and justified by the PI.
- The period of restraint should be the minimum required to accomplish the research objective.
- Animals to be placed in restraint devices should be given training (with positive reinforcement) to adapt to the equipment and the personnel. Animals that fail to adapt should be removed from the study.
- Restraint devices must be kept clean and in good working order.
- Whether, as determined by the IACUC, there is adequate observation of the animal, and at appropriate intervals.
- Veterinary care must be provided if lesions or illnesses associated with the restraint are observed. These concerns, and/or severe behavioral changes, may (at the sole discretion of the Attending Veterinarian) require temporary or permanent removal of the animal from the restraint.
- Unless required to meet research objectives, prolonged restraint must not limit an animal's ability to make normal postural adjustments.
    - Restraint devices should be specifically designed to accomplish research goals that are impossible or impractical to achieve by other means, or without risk to either the animals or personnel.
    - Animals that do not adapt to necessary restraint systems should be removed from the study.

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MULTIPLE MAJOR SURVIVAL SURGERIES

(Approved: October 2015)

No animal assigned to a proposal is to be used for more than one major survival operative procedure unless the multiple procedures are included within one proposal, justified for scientific reasons by the Principal Investigator (PI), and approved by the IACUC. A second major survival surgical procedure may not be performed on the same animal under a separate proposal.

Major Survival Surgery
Major survival surgery penetrates and exposes a body cavity or produces substantial impairment of physical or psychological functions.

An animal needing to undergo an emergency major surgical procedure, as part of proper veterinary care, may still be used in a proposal that requires a major survival surgical procedure as a part of the approved research. There is no requirement for justification in these instances, and the PI and the University Attending Veterinarian should evaluate the suitability of such an animal for the proposed work prior to any procedures being initiated.

Evaluation of Protocols
If an animal will need to undergo two or more major survival surgical procedures as a part of the proposed research, the following information is required for the IACUC to evaluate the protocol:

Scientific Justification
Provide the explanation and justification for the need to have animals undergo multiple major survival surgical procedures. Providing references can be of assistance to the IACUC in this evaluation. The description of the surgical procedure should include the total number of major survival surgical procedures any one animal will undergo, the frequency of such procedures, the approximate duration of each procedure, and the period of time between each surgical procedure.

Species
The species that will undergo this procedure must be clearly stated.

Number of Animals
The specific number of animals that will undergo this manipulation must be clearly stated in the proposal, along with the justification for the group size selected.

Measures to Reduce Pain
The specific measures to decrease pain and distress, including drugs used, as well as the monitoring frequency that will be used to ensure pain/distress is minimized.

Justification
If a major surgery will be performed prior to the animal arriving on campus, including surgeries performed by commercial vendors, the PI should identify and justify any such procedures in the Animal Use Protocol.

The IACUC may require additional updates on animal well-being for multiple survival surgeries and studies where the distinction between major and minor surgery may need to be adjusted according to outcomes. These updates could include, but are not limited to, written requests for information, additional inspections, or requests for scheduling of animal observations.

OCCUPATIONAL HEALTH PROGRAM (OHP)

(Revised and Approved: November 2016)

Occupational Health Program
The Occupational Health Program is an essential element in providing a safe environment for people working in settings with potential exposure to biological, chemical, and physical hazards. Protecting the health and safety of personnel on IACUC protocols at Texas A&M University-Kingsville (TAMUK) is crucial to the continued success of the intuition's mission. Certain personnel can be exposed to higher hazards and risk of adverse health conditions. The TAMUK Occupational Health Program (OHP) is intended to identify those personnel to be included in the OHP and through proper risk assessment, medical surveillance, treatment, and training provide the necessary preventative measures to ensure a safe and healthy work environment at no cost to the personnel.

Enrollment Form
All PIs and personnel listed on IACUC protocols must complete the Occupational Health Program enrollment before approval of the protocol will be granted.

The enrollment form includes a questionnaire which should be completed upon hire or when applicable changes in work occur. The extent and level of participation is determined by assessing the risk posed by exposure to materials, work practices being used, and biohazards with which individuals are working. The purpose of enrollment is to obtain information about job duties which are the basis for risk assessment and reducing risks to the greatest extent possible.

Please see campus rule Occupational Health Program 24.01.01.K0.03

24.01.01.K0.03 Desktop Guide
Protecting the health and safety of employees at Texas A&M University-Kingsville (TAMUK) is crucial to the continued success of our mission to advance knowledge and technologies and bring the finest in health education, promotion and care to Texans.
The Texas A&M University-Kingsville (TAMUK) Occupational Health Program (OHP) is intended to identify those faculty/staff/students to be enrolled/included in the OHP and through proper risk assessment, medical surveillance, treatment, and training, and to provide the necessary preventative measures to ensure a safe and healthy work environment at no cost to the personnel. Enterprise Risk Management (ERM) staff perform periodic workplace assessments and identify operations or environments that may potentially expose faculty/staff/students to known hazards.
Participation and Enrollment in the Occupational Program
Texas A&M University-Kingsville (TAMUK) Occupational Health Program enrollment is required for all individuals who work directly or indirectly with patients, human tissues or wastes; pathogens; animals, animal tissues or wastes, chemicals, sources of radiation, and other physical or biological hazards.

- Individuals listed on an Institutional Biosafety Committee research permit working with agents at BSL1 or above
- Individuals listed on an IACUC research or teaching Animal Use Protocol
- Individuals involved in animal care and housing of animals for research and teaching
- Visitors and collaborators, contract service providers, volunteers
- Other individuals who may reasonably be expected to come in contact with human body fluids, human tissues or waste; animals, animal tissues or wastes; or human disease causing microorganisms as part of their job duties. (this may include Environmental Services, Facilities, Security, Environmental Health & Safety, Lab attendants, Clerical Staff)
- Individuals who work with or are in an area where chemicals are used
- Individuals listed on a radioactive material, laser, or x-ray permit
- Individuals who work in areas with excessive noise or vibration

The extent and level of participation in the OHP is based on a self-reporting risk assessment that takes into account type of exposure, extent and frequency of exposure, and a review of health history by an Occupational Health professional.

TAMUK Occupational Health Program (OHP) Process

Process Step	Sub-Step Description
Step 1: In coordination with the TAMUK Office of Research Compliance, Institutional and Biosafety Committee (IBC), and Institutional Animal Care & Use Committee (IACUC), the Occupational Health Coordinator ensures an OHP Questionnaire enrollment form is completed for all researchers when an IBC or IACUC research protocol is initiated, or when applicable changes occur. The Occupational Health Coordinator also ensures an OHP Questionnaire enrollment form is distributed and completed by research personnel during new hire orientation. **Personnel who decline medical services offered through the OHP program are still required to complete the questionnaire on an annual basis.**	1. The Occupational Health Coordinator, in coordination with Research Compliance Liaison, Principle Investigators, and Supervisors, are responsible for identifying applicable students and staff and ensuring the Occupational Health Program (OHP) questionnaire is completed prior to protocol approval.
	2. The Occupational Health Coordinator receives the OHP questionnaire and conducts a review of the form to ensure accurate contact/demographic information has been annotated on the form.
	3. During the review of the OHP questionnaire, the Occupational Health Coordinator will review whether or not the individual wishes to "decline" participation in the OHP and will also make a determination if there is any type of follow-up action needed, (i.e., incomplete data, request to see a medical provider, required immunizations, etc.).
	4. If needed, the Occupational Health Coordinator will provide necessary authorization to receive additional Occupational Health services (as directed by the Executive Director, Enterprise Risk Management, Occupational Health medical provider, etc.).
	5. Once the questionnaire has been reviewed and necessary services have been rendered, the OHP questionnaire is saved in a secured database and the Master OHP Enrollment excel spreadsheet is updated.
Step 2: The Occupational Health Coordinator ensures compliance with TAMUK rules and procedures and is responsible for tracking the enrollment in medical surveillance programs, and monitoring accomplishment of appropriate occupational health surveillance requirements. **An OHP questionnaire will need to be completed for every protocol if the researcher declined medical services associated with OHP on previous protocol.** **Principal Investigators/Supervisors shall be responsible for implementing procedures in accordance with the OHP.**	1. The Occupational Health Coordinator will conduct ongoing audits to include a monthly review of the Master OHP Enrollment spreadsheet which is used for the notification of participants to complete an Annual medical screening questionnaire.
	2. The Occupational Health Coordinator in coordination with the Research Compliance Liaison, will notify the Principle Investigator and Supervisors that their personnel need to complete the annual medical screening questionnaire.
	3. It is the responsibility of the Principle Investigator to inform the Research Compliance Liaison and the Occupational Health Coordinator in writing if the individual is no longer actively involved in a protocol or is no longer affiliated with TAMUK. This in turn will trigger the disenrollment process.
	4. Once the Occupational Health Coordinator has been notified of the disenrollment, the Master OHP Enrollment excel spreadsheet will be updated by placing the individual in the "Removed" category.

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OCCUPATIONAL HEALTH PROGRAM (OHP)

(Approved: October 2015)

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TRAINING

(Revised: August 2016)

Training

Prior to working with animals, all faculty, staff, and students working with animals must be appropriately qualified to do so in order to ensure the humane treatment of animals. Training is a classic performance standard where the emphasis is on the outcome (i.e., all personnel are qualified to do their jobs). On the job training for those not working directly with animals, but just in the vicinity, for example individuals performing maintenance tasks under the supervision of an animal facility employee, will suffice for reasonable tasks within animal spaces.

Meanwhile, all faculty, staff, and students working on animals protocols must understand the purpose of the IACUC and the key concepts of Replacement, Refinement and Reduction. Although the PHS Policy and Animal Welfare Regulations (AWRs) do not specify a particular program or the frequency with which a program should be offered, the requirement for competence is mandatory.

For those working on research protocols, the TAMUK IACUC has chosen to require the following courses available via the Collaborative Training Initiative (CITI): *Working with the IACUC*, or *Wildlife Research*, based on the type of work to be done. Members of the IACUC will also take the *Essentials for IACUC Members* course.

These training certificates are valid for three years following the completion date, at which time the faculty, staff, and students working on the research protocol will be required to re-take the course to remain eligible to continue working with animals.

The AWRs, in Sec. 2.32 (a) and (b), specify:

> It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel. Training and instruction shall be made available, and the qualifications of personnel reviewed, with sufficient frequency to fulfill the research facility's responsibilities….

Personnel shall receive training in the recognition and alleviation of animal pain, distress, and abnormalities. Similarly, training in the conduct of animal procedures prepares staff to work without causing unnecessary harm to the animal. Technical proficiency also invokes reduction by avoiding wasted animal lives through failed procedures.

Who Should Receive Training?

All personnel should receive training if they interact directly with or work in the vicinity of animals.

For training purposes, staff can be grouped as:

- Researchers (including Principal Investigators)
- Animal care technicians
- Other (e.g., maintenance or support staff)

In some instances, staff may not be clearly divisible into these groups if job responsibilities are more diversified than this classification suggests. For example, facility staff such as animal health technicians may have job functions that include both animal care and research procedures.
Training should also be made available to temporary staff, such as students and visiting scientists. PI's are responsible for identifying these people and assuring that appropriate training is accomplished. Approvals will only be granted once the PI and personnel listed on protocols have completed the required training.

Education and Training for IACUC Members

New Member Orientation

New IACUC member orientation consists of the following: a description of the IACUC and responsibilities; U.S. Government Principles; criteria for membership; authority of the IACUC; protocol review process; continuing reviews of approved protocols, protocol modifications; records; semiannual reviews; roles and responsibilities; and federal regulations. A copy of the *Guide for the Care and Use of Laboratory Animals* is distributed to new members, and they are required to take the additional training module, *Essentials for IACUC Members*.

The objectives of providing this information are the following:

- To introduce members to the role of the IACUC and its evolution
- To provide the basic information necessary for IACUC members to discharge their responsibilities
- To provide a forum for response to, and discussion of, members' concerns and questions