

LAWS AND REGULATIONS "Take-Home" Module (Version 2009B)

To allow greater flexibility for research staff, the Institutional Animal Care and Use Committee (IACUC) has prepared this "self-instruction" module. This packet takes the place of the hour-long lecture or online module and quiz. Please read the enclosed general information, complete the enclosed quiz and **return the quiz by campus mail to: IACUC Certification Coordinator, P.O. Box 210101 or fax to 520-621-8833**. In order to become certified, you may only miss five questions on the quiz. However, the quiz is "open book" and you may consult the materials as you complete the quiz. Please provide an E-mail address if one is available in case there are questions with your exam.

UNIVERSITY ANIMAL CARE (UAC)

Animal Care at the University is centralized under the Office of the Vice President for Research through the UAC unit. A more complete description of this unit and its procedures is available in the *University Animal Care User's Handbook* (<http://www.uac.arizona.edu/invest/userhb/Handbk02.pdf>). A listserv has been set up to inform researchers of alerts concerning their animals or the animal facility. **To subscribe yourself to the Animal_Scoop listserv**, please send an email message to listserv@listserv.arizona.edu with the following information in the body of the email (no subject is required for the message). Subscribe Animal_Scoop <your name here> End or contact Kevin Long (kmlong@email.arizona.edu) if you have any difficulty subscribing to the listserv.

WHO MUST COMPLETE THE MODULE?

All individuals working with animals must be certified in Laws and Regulations, Introduction to Animal Hazards Program, and file a Risk Assessment Questionnaire with Occupational Health. You must also attend the species class which corresponds to the animal model being used for your approved protocols (ie. Rodents, Dog and Cat, Reptiles, Amphibians, Cattle, Horses, Sheep and Goats, Swine, Fish, Poultry, Avian). Many of these can be completed off the website at www.iacuc.arizona.edu/training. Furthermore, **you must attend the class on "Surgery and Anesthesia", if you perform survival surgery or recovery procedures on anesthetized animals**. To register for online classes go to the registration link at <http://www.iacuc.arizona.edu/training>, email iacuctrn@ahsc.arizona.edu or call 621-3931.

WHAT IS AN ANIMAL?

The definition of "animal" varies under specific federal regulations. **Under the Animal Welfare Act, animal is defined as "Any live or dead, vertebrate animal used for teaching, class or laboratory demonstration, student projects, laboratory or field research, or related purposes-regardless of the source of funding."** However, the Act goes on to exclude certain animals. The Public Health Service Policy defines an animal as any live vertebrate animal used in PHS funded research. Here, at the University of Arizona, the IACUC has defined an animal as all living or dead vertebrate animals. If you are working with any animal as defined by our local IACUC, then all IACUC policies apply to your work with animals.

WHY IS THIS MODULE REQUIRED?

The IACUC certification courses offered each quarter are required by two laws, the Animal Welfare Act (P.L. 00-9198 of 1985) and the Health Research Extension Act (P.L. 99-158 of 1985). Both laws require institutions to provide training for persons who use or care for animals.

In addition, there is a powerful scientific incentive for maintaining healthy, well-cared-for animals. **Any person working with animals needs a basic understanding of husbandry, handling and methods to eliminate pain and distress**. The quality of research is improved, by decreasing the number of uncontrolled variables.

A significant number of Americans are opposed to any activity which requires the life of an animal, thereby eliminating dissections or physiological demonstrations from science classes. Furthermore, many

Americans oppose activities which in the past would have been considered harmless such as maintaining a classroom pet and behavioral studies. These people should not be dismissed as isolated fanatics, these beliefs are widespread throughout our society.

All persons who support the use of animals in science must recognize the importance of animal right's organizations in shaping the public's view toward animal use. Legislative staff reports that the *third most frequent* topic for constituent letters is the "abuse" of animals; many of these letters request Congress to *prohibit all use of animals in teaching and research*. In order to combat the negative propaganda of the animal right's crusade and to improve the overall scientific literacy of Americans, biomedical scientists, biologic and agricultural researchers, and life-science educators must encourage the appropriate use of animals in educational settings.

LAWS AFFECTING ANIMAL RESEARCH -

ANIMAL WELFARE ACT:

The Animal Welfare Act was first passed in 1966 and authorized the Secretary of Agriculture to write rules and regulations to prevent the theft of family dogs and cats and to ensure that animals intended for use in research be provided humane care and treatment.

The original law was quite limited and many animals were excluded. However, the law has been amended several times and now includes virtually all warm-blooded vertebrates used for research, teaching or testing. (Research includes field studies as well as more traditional laboratory studies). Farm animals and horses used for biomedical research are included; farm animals used strictly for agricultural research are not at this time covered by this law.

The Act is administered by the U. S. Department of Agriculture-Animal Plant Health Inspection Service - Regulatory Enforcement and Animal Care (**USDA-APHIS-AC**). **At least twice a year, unannounced inspections of research institutions are conducted by USDA-APHIS-AC veterinarians; they have the authority to inspect all housing areas, laboratories and offices where animals or records pertaining to animals are kept.** The AC veterinarian will check for compliance with the thousands of rules and regulations written to implement the law (contained in the Code of Federal Regulations Title 9, Subchapter A, Parts 1-4).

Penalties under the Animal Welfare Act result in penalties which range from monetary fines (\$2500 per day/violation-paid by the Institution) to an issuance of a "Cease and Desist Order". With abuse or life-threatening violations, USDA-APHIS-AC may request that project funds be suspended.

PUBLIC HEALTH SERVICE (PHS) POLICY:

Each institution using animals in PHS sponsored projects must provide a written assurance of compliance (the assurance document is available for review at the Directors' office, College of Medicine Room 1128).

Violations of the PHS Policies may result in loss of ALL PHS funding. Specific requirements are contained in a publication entitled, the Guide for the Care and Use of Laboratory Animals.

ARIZONA GAME & FISH and AGENCIES such as FISH & WILDLIFE SERVICE:

A project using animals covered under State or Federal regulations may not proceed unless the investigator obtains valid permits for collection, purchasing, transporting and holding of these animals. The investigator is responsible for obtaining and maintaining valid permits. If you have questions, please call the protocol coordinator, Mary Durham, at 621-9305.

GOOD LABORATORY PRACTICES (GLP):

The Food and Drug Administration (FDA) requires the creation of Standard Operating Procedures for nonclinical safety assessment studies (such as drug toxicity and efficacy, new medical devices and food additives). When planning a research project where findings will be reported to the FDA, you **must** contact Marilyn Marshall with the Quality Assurance office at 621-1469. There are complex and exacting procedures for record keeping and failure to follow the Standard Operating Procedures may render the study inadmissible for FDA review.

CONTROLLED SUBSTANCE ACT:

Drugs which have the potential for addiction are classified under the law. The Department of Justice, Drug Enforcement Administration (DEA) enforces the law. **A principal investigator must obtain a DEA license to order and use scheduled drugs; all such drugs must be kept under double locked conditions and records of use must be kept for review by DEA officials.** For information, write: U.S. Dept. of Justice, DEA, 3010 N. 2nd St, Suite 301, Phoenix, AZ 85012.

ARIZONA RESEARCH FACILITY PROTECTION ACT:

It is a class 6 felony for a person "to intentionally release an animal that is lawfully confined for scientific, research, commercial or educational purposes without the consent of the owner".

ARIZONA ANIMAL CRUELTY LAW:

The Animal Cruelty law does not exempt research animals from coverage. Therefore, persons committing cruel or abusive acts against research animals could be charged under this law and sentenced to jail.

ARIZONA LAW:

Arizona permits unclaimed pound animals to be released for research. Most animal shelters and pounds in Arizona have chosen not to do so because of adverse public reaction.

In addition to these important laws, there are several associations that have guidelines which impact on research and teaching institutions.

Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC)

AAALAC is a voluntary organization and makes recommendations based on results of site visits. This is a peer review process in which standards are being continually upgraded to reflect current knowledge in laboratory animal science. **Unlike the Animal Welfare Act or the Public Health Service Policy, AAALAC reviews the quality of animal care for ALL animals (including invertebrates).** The University of Arizona is fully accredited.

American Veterinary Medical Association Panel on Euthanasia

The recommendations of the AVMA Panel are the prime reference for methods of euthanasia of animals for both the Animal Welfare Act and the PHS policy.

University of Arizona's Animal Hazard Program

The Interagency Research Animal Committee (IRAC), composed of representatives of federal agencies that use or regulate the use of animals in research, asked the National Research Council (NRC) to conduct a study and produce a report that would provide guidance for protecting the health and safety of workers

who care for and use research animals. The need for such guidance was based both on the recognition of the broad array of occupational hazards when animals are used in research or educational activities and on the absence of authoritative guidance that institutions could use to develop appropriate occupational health and safety programs within their animal research facilities. The IRAC and NRC consider this study particularly important because grantees of the U.S. Public Health Service are required to address the need for an occupational health program. This report, entitled Occupational Health and Safety in the Care and Use of Research Animals, has now been released for compliance by research institutions.

All members of the University of Arizona community with potential exposure to animals or animal by-products are enrolled into the Animal Hazard Program. The program is administered by the Occupational Health Service (OHS) of the Campus Health Center under the direction of the Institutional Animal Care and Use Committee. All members are assessed for risk potential and assigned into a risk category. This is accomplished by a combination of on-site visits by a representative of the OHS and individual risk assessment at the Campus Health Center. Each risk category is monitored according to the potential for hazard exposure. Annually, all supervisory personnel are required to attend a training class. It is expected that costs are minimal to nonexistent to the individual or departments involved.

It is important to remember that participation in this program is mandatory with noncompliance potentially resulting in suspension of research grants and loss of the university's accreditation.

Questions about this program should be directed to Dr. Michael Rand, 626-6705, e-mail: mrand@u.arizona.edu. Appointments for the Occupational Health Clinic may be made at 626-6363.

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC):

Federal law requires each institution which uses animals for research or teaching to form an Institutional Animal Care and Use Committee (IACUC). *The primary mission of the IACUC is to ensure that animals are used and cared for in a responsible manner and that all legal guidelines are observed.*

IACUC FUNCTIONS REQUIRED BY FEDERAL LAW

- A. **Review and approve** all activities involving animals
- B. **Inspect animal housing areas and laboratories** (at least twice a year)
- C. Insure **adequate veterinary care** and oversight
- D. Keep **records** to verify compliance with all regulations
- E. Supervise the **training** required by the law

IACUC members report directly to the official at the institution with authority for compliance (the institutional official for the University of Arizona is Dr. Leslie Tolbert, Vice President for Research & Graduate Studies).

Federal law protects the right of IACUC members to vote without threats of institutional retribution.

Although there is no maximum size limit, PHS requires 5, therefore most IACUCs are composed of 5-15 people with diverse backgrounds. Although each IACUC is unique in composition, it is common to have biomedical scientists from various disciplines, philosophers, medical professionals, teachers, and persons active in local, humane associations.

The Animal Welfare Act requires the IACUC to have at least three members: including a doctor of veterinary medicine, one member who is not affiliated with the institution (an "outside" member) and one scientist.

Generally, the IACUC does not pass judgement as to scientific merit (leaving that function to granting agencies); however, there is no way to dissociate responsible animal use from the question of "what constitutes good and necessary science". Certain proposals will entail pain and distress, if the scientific question being asked is to be answered. The veterinarian holds many roles in research, but their primary role on IACUC is to suggest methods whereby pain and distress can be kept to the absolute minimum. The "outside" members are to represent the concerns of the general community. The "outside" members apply common sense to determine whether or not a specific project warrants the use of animals.

The research investigator should not view the IACUC as "just one more, meaningless, hurdle in the review process"; rather, the IACUC protects the scientist from unfounded criticism by performing an impartial review. **Before a research or teaching project involving animals can begin, an investigator must submit to the IACUC a written proposal outlining the entire project. This written description is termed the "protocol"** The protocol form can be found online at: <http://www.iacuc.arizona.edu/iacucforms>

The IACUC is required by law to show that each investigator has adequately addressed specific questions and topics in the written protocol.

Items Investigator Must Complete for Adequate Protocol Review

- * list and describe training for all persons on project
- * explain the relevance of the proposal,
USE LANGUAGE THAT A LAY PERSON WILL UNDERSTAND
- * explain why non-living systems can not be used for project
- * explain why the particular animal is the best species to use
- * explain how the literature search was conducted
NAME of DATABASE, WHICH KEY WORDS, WHAT TIME PERIOD was SEARCHED?
- * explain how the requested number of animals was derived
- * provide a detailed description of experimental design, include how the data will be collected and analyzed
- * list the location for survival surgery (location must be appropriate for the species)
- * explain how pain and distress will be minimized
DISCUSS TRAINING OF STAFF, PAIN RELIEVING DRUGS, ANIMAL CONDITIONING
- * if pain can not be alleviated, give **scientific justification** for withholding analgesics
- * explain how animals will be killed-method must be humane and approved by the American Veterinary Medical Association

The IACUC has the authority and the responsibility to suspend any activity which is not in compliance with Federal laws, or, which deviates from the approved protocol. Both the Federal Animal Welfare Act and the Public Health Service Policy require the IACUC to report any

suspensions. The funding agency will then conduct their own investigation and may choose to withdraw funding from the project.

When an investigator needs to change any aspect of the approved protocol, they should send a brief memorandum to the IACUC in which the reasons for the changes are outlined or file the appropriate IACUC forms available on the IACUC website at www.iacuc.org. The amendment cannot be implemented until proof of IACUC review and approval is received. Please remember to write the IACUC and request to amend your protocol(s) when any person is added to the research project(s).

Investigators MUST strictly observe ALL procedures as they are described in the approved protocol. Institutions have received violations and fines when investigators have made relatively minor changes in their projects without IACUC approval for the amendments:

example: Dr. Yaz has an IACUC approved protocol which states that rabbits will be humanely killed with an injection of pentobarbital. His graduate student says that it would be more humane if rabbits were first anesthetized with halothane. Dr. Yaz must request IACUC approval for amending the method of euthanasia to include the halothane BEFORE he initiates this change in procedure.

example: Dr. Richie has an approved protocol which allows him to terminate two rats each Spring and Fall semester for a physiology class. He will be teaching the same exact class during the summer session, so he **WRONGLY BELIEVES** that he can simply get two extra rats. (Dr. Richie must ask the IACUC to amend his protocol to add the two additional rats. Failure to do so will mean the institution is in violation).

example: Dr. Mandrup has himself and one graduate student listed on the protocol as persons working with animals. Several undergraduate students wish to work in his laboratory to gain experience in research techniques. Dr. Mandrup **WRONGLY BELIEVES** that these students do not need to be listed on the protocol, since either he or his graduate student is always present to supervise the undergraduates.

At least twice a year, the IACUC must inspect all housing areas and laboratories where animals are used. University Animal Care staff have been designated as official representatives of the IACUC and will also perform periodic inspections of areas where animals are used for teaching and research.

One additional responsibility of the IACUC is to supervise the training of all persons using or caring for animals. The laws are quite specific as to which topics **must be covered**. This take-home module on "Laws & Regulations" includes the required topics in the order in which they are written below:

REQUIRED BY LAW IN TRAINING PROGRAM

- a) 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
- b) Training and instruction shall be made available, and the qualifications of personnel reviewed, with sufficient frequency to fulfill the research facility's responsibilities under this section.
- c) Training and instruction of personnel must include guidance in at least the following areas:
 1. Humane methods of animal maintenance and experimentation, including:
 - The basic needs of each species of animals;

- Proper handling and care for the various species of animals used by the facility;
Proper pre-procedural and post-procedural care of animals; and
Aseptic surgical methods and procedures;
2. The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress;
 3. Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility;
 4. Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, committee, member or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act;
 5. Utilization of services (e.g., National Agricultural Library, National Library of Medicine) available to provide information:
 - On appropriate methods of animal care and use;
 - On alternatives to the use of live animals in research;
 - That could prevent unintended and unnecessary duplication of research involving animals, and;
 - Regarding the intent and requirements of the Act.

CONCEPT AND METHODS TO LIMIT ANIMAL USE: The underlying theme of legislation involving research animals is the need to *reduce the numbers of animals used in research, and to minimize the discomfort of those animals which are used:*

1) ***Unnecessary duplication of research should be avoided for scientific and ethical reasons. Replication of experiments may be reasonable, but the investigator must provide sufficient information to justify why an experiment needs to be repeated.***

2) The number of animals should be the minimum necessary to produce valid results and the investigator must clearly present to the IACUC the method whereby the number of requested animals was calculated. **(It may be helpful if proposals are reviewed by a statistician before they are submitted to the IACUC).**

3) **When appropriate, a non-animal substitute should be used, or a species of "lower" order (e.g. using a frog instead of a rat or, a rat instead of a dog).**

Although a living organism is the appropriate model for many projects, **each investigator is required to consider the use of non-living, or alternative model systems.**

example: There is a computer program which allows the operator to select a particular venous return, in return, the heart rate and stroke volume will then change. This program models the Starling law of the heart.

Federal and many private granting agencies require a database search for using alternatives to animals in research. Up to now, the world of database searching for alternatives has been confusing and frustrating. The National Library of Medicine, NIH has just made a search engine available that is very easy to use at:<http://toxnet.nlm.nih.gov/altbib.html>. You can search by keyword and/or category (e.g., carcinogenesis). Bookmark this site and use it for your animal use protocol submissions to the IACUC!

UTILIZATION OF SERVICES: Before a project begins, an investigator must complete a literature review:

1) to be assured that the project is not intentionally duplicating another project;

2) to provide a scientific basis for the choice of the model;

3) to be assured that a non-living alternative model does not exist. Although there are many sources which may be consulted, the following are specifically designed to provide alternatives to the use of live animals and methods to reduce pain and distress:

A. Animal Welfare Information Center, National Agricultural Library, Room 304, Beltsville, MD 20705 (301 344-3212). The publication *Animal Welfare Information Center Scope Notes for Indexes* outlines available subject areas. The NAL provides computerized bibliographic retrieval service through its in-house database AGRICOLA.

B. Center for Alternatives, Johns Hopkins University School of Hygiene and Public Health, Baltimore, MD 21205 (301 955-3343). Publishes a newsletter on techniques to reduce the numbers of animals in product safety testing.

C. National Library of Medicine, Coordinator of Veterinary Affairs, Bethesda, MD 20892 (301 496-6308). Publishes *Current Bibliographies in Medicine*, including those dealing with pain, anesthesia, and analgesia in animals; care and use of animals; and laboratory animal welfare.

PROPER USE OF ANESTHETICS, ANALGESICS, and TRANQUILIZERS: Investigators are required by law to use the appropriate drugs for sedation, analgesia and anesthesia for any procedure that causes more than the pain associated with a needle prick, UNLESS WITHHOLDING THE DRUG IS JUSTIFIED FOR SCIENTIFIC REASONS AND APPROVED BY IACUC!

The rule is that if something causes pain in humans, the same stimulus is considered to cause pain in an animal. Therefore, the investigator must provide justification for any procedure which is likely to cause pain in a human.

SURVIVAL SURGERY: No matter what the species, survival procedures must be conducted under aseptic (sterile) conditions! Failure to observe aseptic surgical technique activates the immune response and may introduce bacteria into the site.

Requirements for All Survival Surgery (Aseptic Conditions)

- * wear sterile gloves
- * use sterilized instruments
- * prepare surgical site with povidone iodine and alcohol (hair clip followed by three separate scrubs)
- * maintain sterile field until skin is closed
- * provide close supervision until animal is awake

All survival surgical procedures for vertebrates "higher" than rodents MUST BE conducted in the surgical suite located within University Animal Care or as approved by IACUC. The suite contains a surgical support area (where packs may be wrapped and autoclaved), an animal preparation area, a dressing area for the surgeons, an operating room and an area for post-operative recovery.

Survival surgery for rodents or "cold-blooded" animals may be conducted in the laboratory-but there MUST BE three, separate dedicated areas. There must be separate areas for preparing the animal (clip and scrub site), for the aseptic surgery, and for the post-operative recovery period.

Federal law allows survival, surgical procedures on all types of animals to be conducted in the field, provided they are performed under aseptic conditions.

CARE FOLLOWING SURGERY: Post-surgical care at the minimum requires that animals be observed until they have regained the "righting reflex", the "swallow reflex" and are breathing

without support. An additional heat source is needed for mammals during the immediate post-operative period.

NON-SURVIVAL SURGERY: Projects wherein animals of any species are anesthetized, surgically affected and euthanized at the end of the project (without ever regaining consciousness) may occur in the laboratory.

NO ANIMAL, WITHOUT SCIENTIFIC JUSTIFICATION AND APPROVED BY IACUC, MAY BE USED FOR MORE THAN ONE PROTOCOL WHICH REQUIRES A SURVIVAL SURGERY, OR PRODUCES A PERMANENT HANDICAP. When an investigator believes that the scientific aims justify the use of an animal on multiple surgical protocols, that investigator must convince the IACUC that there is no alternative to such use.

EUTHANASIA: Euthanasia means the humane killing of an animal by a method which produces rapid unconsciousness and subsequent death without evidence of pain or distress. **Generally, the method of euthanasia for a given species must be consistent with the Report of the American Veterinary Medical Association Panel on Euthanasia. Alternative methods can't be approved by the IACUC, unless the investigator provides sufficient scientific justification.**

MECHANISM FOR REPORTING PROBLEMS: **Both the Animal Welfare Act and the Public Health Service Policy require each institution to investigate all complaints about suspected animal abuse or non-compliance with the laws.**

For any serious or life-threatening complaint (determined by the IACUC), the results of the investigation must be forwarded to Federal authorities.

Any person (student or employee) who reports an alleged violation is protected from retaliatory action by both State and Federal law.

HOW TO REPORT PROBLEMS or DEFICIENCIES IN ANIMAL CARE AND TREATMENT

1. Should there be a minor problem in husbandry, please call one of the **UAC facility coordinators:** Cheryl Johnson (626-6706) at the College of Medicine facility or Miguel Diaz (621-1621) at the Central Animal Facility on campus.
2. **Should there be any problem in animal care during the conduct of a research or teaching project, please notify the Chair of the Institutional Animal Care and Use Committee: Dr Charles Sterling (621-4580) and/or the Director of University Animal Care: Dr Susan Wilson-Sanders (626-6702).**
3. In addition, **a complaint may be made directly to the office of the Vice-President for Research: Dr Leslie Tolbert (621-3513).**

ROOM ORDER IN UAC FACILITIES: **The primary mechanism for controlling the spread of disease agents is to separate groups of animals according to health status.** UAC maintains six levels of separation and designates the "most clean" animals as "A" and the "most dirty" animals as "F". Each room has a large letter posted on the outside of the door. Should you have any questions, please speak with the facility supervisor. You may enter rooms in the same order that the letters fall within the alphabet.

example: You may enter an "A" room before a "C" room, before a "D" room and lastly a "F" room.

You may NEVER enter two animal rooms the same day in the reverse order.

example: You have mice in an "A" room and rats in a "B" room. You may not work in the "B" room and later the same day, enter the "A" room.

WHERE CAN ANIMALS BE KEPT: The College of Medicine Facility is located in the Basic Science Building at the Arizona Health Science Center. The Central Animal Facility is located just south of the Pharmacy/Microbiology building and the Psychology Facility is located just east of Modern Languages building on main campus. Unless special approval is granted by the IACUC, vertebrate animals must be housed in one of these three sites. When the IACUC approves a different location, specific housing conditions must be maintained and the area will be routinely inspected by University Animal Care personnel.

Without IACUC approval, it is illegal to keep any vertebrate animal for greater than 12 hours in any area (for example: laboratories, offices, dorm rooms, outside pens, homes). Furthermore, pets or wild caught animals ARE NOT ALLOWED AT THE UNIVERSITY without IACUC approval.

ANIMAL PROCUREMENT: Specific requirements and information can be found in the *University Animal Care User's Handbook*. However, the important restrictions include:

If an investigator has more than one approved animal protocol, the protocol control number under which the animal was ordered MUST BE the actual project for which the animal is used!

No live, vertebrate animal may be obtained without prior IACUC approval, this includes animals which are purchased, donated or collected in the field.

All requests for animals (or animal parts/tissues) must be routed through the Animal Order Specialist at 626-4511.

Animal use needs to be closely monitored for the following reasons:

- 1) to ensure that animals are legally obtained and transported according to strict federal guidelines. **In general, animals must be transported in university owned vehicles so that all federal transportation guidelines may be observed.**
- 2) to ensure that the number of animals on an approved protocol is not exceeded in a given year
- 3) to allow the University of Arizona to submit the proper records of annual animal use to federal authorities.

This packet may be kept for future reference.

References:

1993 Report of the AVMA Panel on Euthanasia, J. Am. Vet. Med. Assoc. 202(3): 229-249

Education and Training in the Care and Use of Laboratory Animals, National research Council, National Academy Press, Washington, DC 1991

Essentials for Animal research, A Primer for Research Personnel, National Agriculture Library, Beltsville, MD 1990

Alternative to the Use of Live Vertebrates in Biomedical Research and Testing, ILAR News, 32 (1): A1-A18 1990.

Who To Contact For Commonly Asked Questions

<u>QUESTION</u>	<u>CONTACT PERSON</u>	<u>PHONE</u>
Anesthesia/Analgesia	Dr Michael Rand	626-6705
Animal Hazard Program	Kathy Stollberg Dr Michael Rand	626-7304 626-6705
Animal Husbandry Problems, AHSC	Cheryl Johnson	626-6706
Animal Husbandry Problems, CAF	Miguel Diaz	621-1621
Animal Husbandry, Breeding	Cindy Richner	626-6270
Animal Model to Use	Dr Michael Rand	626-6705
	Dr Susan Sanders	626-6702
Animal Orders	Wendy Keswater	626-4511
Animal Welfare	Dr Susan Sanders	626-6702
Assistance in Planning Studies	Dr Dave Besselsen	621-1564
	Dr Peder Cuneo	621-2356
	Dr Paula Johnson	621-3483
	Dr Michael Rand	626-6705
	Dr Susan Sanders	626-6702
Billings/statements/IBF	Rachel Patrick	626-4701
Euthanasia Techniques	Kathy Stollberg	626-7304
	Dr Michael Rand	626-6705
Facility Maintenance, AHSC or CAF	Tim Ruddy	626-6702
Facility/Program Long-range Planning	Dr Susan Sanders	626-6702
Farm Animal Use	Dr Peder Cuneo	621-2356
IACUC Problems or Complaints	Dr Charles Sterling	621-4580
	Mary Durham	621-9305
IACUC Investigator Certification Program	Grace Aranda	621-3931
Keys & Security Access Cards, AHSC	Cheryl Johnson	626-6706
Keys & Security Access Cards, CAF	Miguel Diaz	621-1621
Pathology Support Services	Dr Dave Besselsen	621-1564
	Jessie Loganbill	626-7661
Per Diem Rates	Rachel Patrick	626-4701
PROTOCOLS:		
Planning New Studies	Dr Michael Rand	626-6705
Protocol Review, Administrative Questions	Mary Durham	621-9305
Protocol Review, Scientific Questions	Dr Paula Johnson	621-3483
	Dr Michael Rand	626-6705
Radioisotope, Room Use Approval	Cheryl Johnson	626-6706
Space for Animals, Current Studies, AHSC	Wendy Keswater	626-4511
Space for Animals, Current Studies, CAF	Miguel Diaz	621-1621

2009 EVALUATION OF "TAKE HOME" LAWS & REGULATIONS MODULE - Version B

Thank you for completing this "self-instruction" module. Please take time to complete the short evaluation form. Your comments are valuable in designing the style and substance of future certification courses to make this process effective for research staff. (circle one)

Was this packet useful? YES NO

Did you learn anything new? YES NO

Was the training adequate? YES NO

Was the packet too long? YES NO If so, suggested items to cut:

Were the questions too difficult or was it hard to find answers to the questions? YES NO

Did you like the self-instruction packet? YES NO, I would you prefer to attend a lecture.

Do you have any other comments or suggestions to improve this module? Topics not covered?

LAWS & REGULATIONS (Version 2009B)

Your Name(print): _____ Department: _____

Employee ID# _____ Investigator: _____ Lab phone: _____

E-mail _____ Confirm I passed ____ (Must provide email address)

The Animal Scoop ListServe is important because:

- 1) It allows a fast and sure way to alert all research staff using animals of any emergency situation
- 2) It provides updates regarding policy or service within University Animal Care.
- 3) It provides quick notification of things of vital concern to your research
- 4) It keeps labs informed by requiring that at least one member of each laboratory utilizing animals must subscribe to Animal Scoop.
- 5) **ALL OF THE ABOVE** - **HINT:** This is the correct answer. To subscribe yourself to the Animal_Scoop listserv, send an email message to listserv@listserv.arizona.edu with the following information in the body of the email (no subject is required for the message). Subscribe Animal_Scoop <your name here> End or contact Kevin Long (kmlong@email.arizona.edu) if you have any difficulty subscribing to the listserv.

CERTIFICATION NOT GIVEN IF INFORMATION IS NOT READABLE OR INCOMPLETE

In order to become certified, you may miss FIVE or less questions. The notes may be consulted when answering this quiz. Please circle the "T" if "true", or the "F" if "false".

1. T F All individuals working with animals must be certified in Laws and Regulations, Introduction to Animal Hazards Program, and file a Risk Assessment Questionnaire with Occupational Health.
2. T F You must attend the class on "Surgery and Anesthesia", if you perform survival surgery or recovery procedures on anesthetized, vertebrate animals.
3. T F Under the Animal Welfare Act, animal is defined as "Any live or dead, vertebrate animal used for teaching, class or laboratory demonstration, student projects, laboratory or field research, or related purposes-regardless of the source of funding.
4. T F The IACUC certification courses offered each quarter are suggested, but not required by two laws, the Animal Welfare Act and the Health Research Extension Act.
5. T F At least twice a year, unannounced inspections of research institutions are conducted by the Humane Society veterinarians who have the authority to inspect all housing areas, laboratories and offices where animals or records pertaining to animals are kept.
6. T F Penalties under the Animal Welfare Act range from monetary fines to an issuance of a "Cease and Desist Order". With abuse or life-threatening violations, USDA-APHIS-AC may request that project funds be suspended.
7. T F Violations of the PHS Policies do not result in loss of ALL PHS funding.

8. T F A project using animals covered under State or Federal regulations may not proceed unless the investigator obtains valid permits for collection, purchasing, transporting and holding of these animals. The investigator is responsible for obtaining and maintaining valid permits.
9. T F The Food and Drug Administration suggests but does not requires the creation of Standard Operating Procedures for nonclinical safety assessment studies.
10. T F A principal investigator must obtain a DEA license to order and use scheduled drugs; all such drugs must be kept under double locked conditions and records of use must be kept for review by DEA officials.
11. T F It is a class 6 felony for a person "to intentionally release an animal that is lawfully confined for scientific, research, commercial or educational purposes without the consent of the owner".
12. T F The Animal Cruelty law does not exempt research animals from coverage. Therefore, persons committing cruel or abusive acts against research animals could be charged under this law and sentenced to jail.
13. T F Unlike the Animal Welfare Act or the Public Health Service Policy, AAALAC is a voluntary organization that reviews the quality of animal care for ALL animals.
14. T F All members of the University of Arizona community with potential exposure to animals or animal by-products are enfolded into the Animal Hazard Program.
15. T F It is important to remember that participation in the Animal Hazard Program is mandatory with noncompliance potentially resulting in suspension of research grants and loss of the university's accreditation.
16. T F Federal law does not require each institution which uses animals for research or teaching to form an IACUC.
17. T F IACUC members report directly to the president of the university.
18. T F The primary mission of the IACUC is to ensure that animals are used and cared for in a responsible manner and that all legal guidelines are observed.
19. T F Federal law protects the right of IACUC members to vote without threats of institutional retribution.
20. T F PHS Policy requires the IACUC to have at least three members: including a doctor of veterinary medicine, one member who is not affiliated with the institution (an "outside" member) and one scientist.
21. T F Before a research or teaching project involving animals can begin, an investigator must submit to the IACUC a written proposal outlining the entire project. This written description is termed the "protocol."

22. T F The IACUC has the authority and the responsibility to suspend any activity which is not in compliance with Federal laws, or, which deviates from the approved protocol. Both the Federal Animal Welfare Act and the Public Health Service Policy require the IACUC to report any suspensions.
23. T F When an investigator needs to change any aspect of the approved protocol, they should send an amendment which can be implemented until proof of IACUC review and approval is received.
24. T F It is suggested but not mandatory that investigators observe all procedures as they are described in the approved protocol, though no Institution has received violations or fines when investigators make changes in their projects without IACUC approval for the amendments.
25. T F At least twice a year, the IACUC must inspect all housing areas and laboratories where animals are used. University Animal Care staff have been designated as official representatives of the IACUC and will also perform periodic inspections of areas where animals are used for teaching and research.
26. T F The IACUC has the responsibility to supervise the training of all persons using or caring for animals.
27. T F The underlying theme of legislation involving research animals is the need to reduce the numbers of animals used in research, and to minimize the discomfort of those animals which are used.
28. T F Duplication of research cannot be avoided for scientific and ethical reasons. Replication of experiments is required and the investigator must justify why an experiment does not need to be repeated.
29. T F It is never helpful if protocols are reviewed by a statistician before they are submitted to the IACUC.
30. T F When appropriate, a non-animal substitute should be used, or a species of "lower" order.
31. T F Before a project begins, an investigator must complete a literature review: to be assured that the project is not unintentionally duplicating another project; to provide a scientific basis for the choice of the model; and to be assured that a non-living alternative model does not exist.
32. T F Investigators are required by law to use the appropriate drugs for sedation, analgesia and anesthesia for any procedure that causes more than the pain associated with a needle prick, unless withholding the drug is justified for scientific reasons and approved by the IACUC.
33. T F The rule is that if something causes pain in humans, the same stimulus is considered to cause pain in an animal.

34. T F No matter what the species, survival procedures aren't required to be conducted under aseptic (sterile) conditions.
35. T F All survival surgical procedures for vertebrates "higher" than rodents MUST BE conducted in the surgical suite located within University Animal Care or as approved by IACUC.
36. T F Survival surgery for rodents or "cold-blooded" animals must never be conducted in the laboratory.
37. T F Federal law allows survival, surgical procedures on all types of animals to be conducted in the field, provided they are performed under aseptic conditions.
38. T F Post-surgical care is not required in animals.
39. T F Any animal may be used for more than one protocol which requires a survival surgery, or produces a permanent handicap.
40. T F The method of euthanasia for a given species must be consistent with the Report of the American Veterinary Medical Association Panel on Euthanasia. Alternative methods can't be approved by the IACUC, unless the investigator provides sufficient scientific justification.
41. T F Neither the Animal Welfare Act or the Public Health Service Policy require an institution to investigate complaints about suspected animal abuse or non-compliance with the laws.
42. T F For any serious or life-threatening complaint, the results of the investigation must be forwarded to Federal authorities.
43. T F A person who reports an alleged violation about suspected animal abuse or non-compliance with the laws is not protected from retaliatory action by both State and Federal law.
44. T F Should there be any problem in animal care during the conduct of a research or teaching project the Chair of the Institutional Animal Care and Use Committee, or the Director of University Animal Care should be notified.
45. T F A complaint may be made directly to the office of the Vice-President for Research.
46. T F The primary mechanism for controlling the spread of disease agents is to separate groups of animals according to health status.
47. T F UAC maintains six levels of separation and designates the "most clean" animals as "A" and the "most dirty" animals as "F". Each room has a large letter posted on the outside of the door. You may enter rooms in the same order that the letters fall within the alphabet. Example: You may enter an "A" room before a "C" room, before a "D" room, etc.

48. T F If an investigator has more than one approved animal protocol, the protocol control number under which the animal was ordered does not have to be the actual project for which the animal is used.
49. T F Live, vertebrate animals may be obtained without prior IACUC approval, including animals which are purchased, donated or collected in the field.
50. T F Animals must be transported in university owned vehicles so that all federal transportation guidelines may be observed.

DON'T LEAVE ANY QUESTIONS UNANSWERED, THEY WILL BE MARKED INCORRECT!

Once completed, fax quiz to 520-621-8833