Institutional Animal Care & Use Committee (IACUC)

Orientation & Training

For

Animal Users in Teaching and Research

July 1, 2008
INTRODUCTION

All personnel who are involved in the use of animals for either teaching or research at Virginia Tech have a responsibility for appropriate animal care and use. Further, each individual is accountable, by law, to conform to the basic regulations and policies governing animal use at this university. These regulations and policies cover:

a) The acquisition, care and use of animals
b) Efforts to minimize pain and distress of animals
c) The training of personnel using animals
d) Consideration of alternatives to animal use.

The purpose of this Online Training Session is to provide the VT-Specific IACUC training as required by University policy and Federal regulations. Further information regarding the care and use of animals at Virginia Tech is available at the URL below or by contacting staff at either the IACUC Office, Central Vivarium, Derring Hall Vivarium or CVM TRACSS (Teaching and Research Animal Care Support Services).

The IACUC website is: http://www.acc.vt.edu/
TRAINING REQUIREMENTS

A multi-level approach will be adopted to provide a variety of training programs for all Faculty, Staff (teaching, research and/or husbandry), Residents, Interns and Graduate Students (MS, PhD) at Virginia Tech who utilize animals as part of their daily responsibilities, including teaching or research. This training will occur on three levels:

Level I - Basic IACUC Core Compliance Assurance Training [all users]

All researchers and staff using animals in teaching or research and students using animals in research must receive **basic uniform compliance training that MUST be completed before animal use may begin (effective 8/1/08).**

Note: Occupational Health and Safety Training (including Zoonoses Training) is also mandatory and is available online. It is required of all animal users/handlers listed above, plus non-animal users with significant animal exposure (usually airborne) prior to the start of any animal use. This training is available at [www.acc.vt.edu/occhealth.html](http://www.acc.vt.edu/occhealth.html).

This training has three components:

a) Core IACUC training (accomplished online at the AALAS Learning Library website, see below)
b) VT-Specific IACUC training (usually accomplished online via this course)
c) Forms/Records training (general topic addressed in this course; species-specific information usually communicated via Animal Care Facilities personnel or the Office of Animal Resources/Office of University Attending Veterinarian)

These training elements will provide:

- An overview of federal laws, regulations, and guidelines
- An overview of Virginia Tech policies and procedures
- An overview of the Virginia Tech animal care and use program
- An introduction to the Occupational Health and Safety programs at Virginia Tech which are specific to individuals who handle, care for, and use laboratory animals
- A mechanism for reporting concerns about inappropriate handling, care, or use of animals in teaching and research at Virginia Tech
- A discussion about ethical issues and societal concerns about the use of animals in research, teaching, and testing
- Virginia Tech forms and record keeping requirements.
- Provision of adequate veterinary care

The **Core IACUC training** is available online through the AALAS Learning Library. Instructions for enrolling in this training module and use of the module are available at [AALAS Learning Library](http://www.aalas.org/learninglibrary)
http://www.acc.vt.edu/ on the Training Information page, or you can use the direct link: http://www.acc.vt.edu/IACUC_Core_PI_Online_Intructions.doc.

In addition, the Virginia Tech IACUC Orientation and Training hardcopy training manual contains the instructions to enroll in the AALAS Learning Library. Those instructions are located in Appendix 1 and the text in the Core IACUC training course, entitled Working With the IACUC: Non-VA Version, is provided in Appendix 2. Contact the IACUC office for a copy of this manual, if desired. It is not required as all training may be completed online.

The VT-Specific IACUC training will be provided online via this tutorial but is occasionally offered live by Dr. David Moore, the University Attending Veterinarian. The slides used in Dr Moore’s talk have been included in Appendix 3 of the Virginia Tech IACUC Orientation and Training hardcopy training manual, the text of which was utilized in creating this tutorial.

Animal Record/Forms training is available through the supervisor of your animal care facility, the Attending Veterinarian’s office or your Principal Investigator. It is your responsibility to ensure that records are accurately maintained and appropriate to the species. Please seek out this training before any animal use in research or teaching is begun.

Level II - Species Specific Training [users of particular species]

Species-specific training will be provided to researchers and staff on the humane care and use for the species (single or multiple) that they will be using in their teaching, research or husbandry. This training will include:

- Biology and care of the species to be used
- Basic research techniques for the species to be used (handling, restraint, injection techniques, blood collection techniques, euthanasia)
- Observation/health monitoring
- Proper use of anesthetics, analgesics, and tranquilizers (as applicable to the study protocol)
- Assessment of alternate endpoints for studies involving USDA Pain Category E protocols.
- Acceptable euthanasia methods for the species to be used
- Necropsy techniques and gross anatomy

Level III - Specialized Procedures [taught as needed by mentor professor and/or training staff for each protocol or animal care procedure]

A third level of training will involve more sophisticated training in anesthesia and surgical techniques if these are required in their teaching labs or research projects. This training will
include:

- Proper pre-procedural and post-procedural (usually postoperative) care of animals
- Aseptic surgical methods and procedures
- Proper use of anesthetics and postoperative analgesics
- Special techniques - catheterization, vascular cutdowns, abdominal or thoracic surgical procedures
- Assessing pain/distress

Legislative Requirements for Training of Personnel Using Animals in Teaching and Research

Training is compulsory for all faculty, staff and graduate students handling animals during teaching or research as required by a number of legislative acts. These include:

I. Animal Welfare Act Regulations (AWAR) Requirements for Training:

The USDA administers a Federal Law known as the Animal Welfare Act, PL 89-544 and its amendments. Groups that conduct research with animals are subject to regulation by this Act. The Animal Welfare Act regulates the use of all warm-blooded vertebrates in research except birds, rats and mice bred exclusively for research. The regulations deal with housing, handling, feeding, watering, sanitation, ventilation, transportation, separation of species and veterinary care for these animals. This act also requires that animal facilities record and total their yearly animal inventory and use and submit this (on an appropriate form) to the USDA.

In order to ensure compliance with these regulations, the USDA periodically sends an inspector to the research facility to conduct an unannounced site visit. The inspector evaluates the animals, facility and animal records of the institution. Any violations are listed on an inspection form and forwarded to the institutional officer for correction. The USDA has the authority to stop research at an institution that does not treat animals in accordance with the law.

Animal Welfare Act Regulations (AWAR) Training Requirements:

Sec. 2.32 (Personnel qualifications) of the AWAR states that:

1. 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.
2. 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 and Sec. 2.31.

3. Training and instruction of personnel must include guidance in at least the following areas:

1. Humane methods of animal maintenance and experimentation, including:
   (i) The basic needs of each species of animal;
   (ii) Proper handling and care for the various species of animals used by the facility;
   (iii) Proper pre-procedural and post-procedural care of animals; and
   (iv) 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;
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:
   (i) On appropriate methods of animal care and use;
   (ii) On alternatives to the use of live animals in research;
   (iii) That could prevent unintended and unnecessary duplication of research involving animals; and
   (iv) Regarding the intent and requirements of the Act.

II. Public Health Service (PHS) Policy Requirements for Training

PHS Policy requires the IACUC, when reviewing protocols, to determine that personnel conducting procedures involving animals are appropriately qualified and trained. Institutions are required to include in their NIH/Office for Laboratory Animal Welfare Assurance a "Synopsis of [the] training or instruction in the humane practice of animal care and use, as well as training or instruction in research or testing methods that minimize the number of animals required to obtain a valid results and minimize animal distress, offered a scientist, in all technicians, and other personnel involved in animal care, treatment, or use." PHS policy does not specify any type of species-specific training, but it does require that Assured institutions use the “Guide” as a basis for their animal care and use program.
III. Training Recommendations in the "Guide for the Care and Use of Laboratory Animals"

The "Guide" recommends that individuals who care for or use animals should be properly trained, and that the institution has a responsibility for providing either formal or on-the-job training for personnel. Training of animal care personnel is necessary to implement an effective animal care and use program and to foster humane animal care and use. Investigators and other personnel who perform surgery, administer anesthesia, or perform other manipulations must be properly trained to accomplish these tasks in a humane and scientifically acceptable manner.
RECORDKEEPING REQUIREMENTS

Virginia Tech and USDA-APHIS-AC Policies on animal use require **written documentation of all procedures performed on live animals**. In this manner, we can track the use of animal(s) over time, as well as provide mandatory reports to regulatory oversight or accrediting agencies, e.g. IACUC, USDA, AAALAC International, and the DEA. These agencies will also inspect our animal records during either planned or unplanned inspection visits to our facilities.

Per USDA’s Policy #3, Veterinary Care, animal health records must be sufficiently detailed to convey necessary information to all personnel involved in an animal’s care and be sufficiently comprehensive to demonstrate the delivery of adequate health care, consistent with professional standards. **Individual records** will be maintained for animals used individually and located at the University for prolonged periods of time, e.g. dogs, cats, horses, goats, and ferrets. **Group records** (i.e. cage cards) may be maintained for animals housed and treated as a group, e.g. mice and rats.

Specifically, health records for USDA regulated species must include:

- Identity of the animal
- Descriptions of any illness, injury, distress and/or behavioral abnormalities and the resolution of any noted problem.
- Dates, details and results (if appropriate) of all medically-related observations, examinations, test and other such procedures.
- Dates and other details of all treatments, including the name, dose, route, frequency, and duration of treatment with drugs or other medications. (A “check-off” system to record when treatment is given may be beneficial.)
- Treatment plans should also include a diagnosis and prognosis, and detail the type, frequency, and duration of any treatment and the criteria and/or schedule for re-evaluation(s) by the attending veterinarian.
- Surgical records should also include detailed pre- and post-, as well as intra-operation, notes.

Please contact the facility supervisor for the area in which your animals are housed for specific forms and record keeping requirements. The information required will include, but may not be limited to, all procedures performed on live animals (including surgery), the types and amounts of drugs administered (e.g. anesthetic agents, analgesics, tranquilizers), complications arising from any procedures undertaken, as well as objective data on the routine health status of the animal.

**All animal records will be maintained in close proximity to the animals.** At the time of termination of animals from a protocol, the animal’s records will be removed from the animal room/area and filed in the Vivarium office for a **minimum of three years.**
**Controlled substance records** must be maintained in accordance with the Code of Federal Regulations on Food and Drugs, Title 21. These records must be kept with controlled substances in a secured area as per University policy and federal regulations.
VIRGINIA TECH INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) OVERVIEW

Membership:

The IACUC membership is comprised of faculty representatives from Virginia Tech departments or colleges using animals in teaching or research. The Attending Veterinarian and Biosafety Officer are also members of VT’s IACUC.

Faculty members are nominated by their Department Heads and are appointed by the designated Institutional Official [IO] (the Vice President for Research). IACUC’s are also required to have one community and non-scientist member and this person is also appointed by the Institutional Official. All members serve for 3 years, except for the Attending Veterinarian and the Biosafety Officer who are voting *ex officio* members.

Administration:

The IACUC Chair is elected annually by the Committee membership. The Chair and the IACUC are provided with administrative support by the IACUC Administrator and the IACUC Senior Administrative Assistant. The Post Approval Monitoring Officer also supports the IACUC via oversight of animal use in teaching and research.

IACUC Protocols and Their Significance:

IACUC-approved animal use protocols represent a “contract” between the Principal Investigator (PI), the IACUC, and the federal government. The IACUC is considered the representative of the federal government within an institution, thus all applicable laws are binding and maintained through the IACUC.

**NO CHANGES** in:
- personnel,
- procedures, or
- animal numbers

can be made without first obtaining amendment approval from the IACUC. Further, a copy of each active protocol must be kept in the PI’s lab or similar area for each access to and reference by study personnel. The Post Approval Monitoring audits will verify research staff adherence to the approved protocol(s).
Who May Submit IACUC Protocols:

Only VT faculty can be designated as the Principal Investigator (PI), and thus a protocol must be submitted by that faculty member. For questions as to what level of faculty member is eligible to submit a protocol, please contact the IACUC office.

Graduate students, other students, and staff may be listed as Co-PI(s), but cannot submit a protocol that has not been first reviewed and approved by the PI.
IACUC PROTOCOL REVIEW PROCESS

Source of IACUC Submission Forms

IACUC protocol submission forms are available on the IACUC website: www.acc.vt.edu. Please note that ACC is the former acronym for the IACUC – the Animal Care Committee.

Because the forms are updated periodically, PI’s are advised to download new blank forms as needed directly from the IACUC website. This is due to the fact that, after a limited grace period upon release of new forms, new submissions on old forms are no longer accepted.

Types of Protocol Submission Forms:

1. **Main submission forms** for proposed uses of vertebrate animals in research or for instruction/teaching labs:
   - “New Protocol Review Form – Instruction”

2. **Appendices A through H** are selected and indicated by the PI in Section 12, item #6, of the above New Protocol Review Form. The appendices required vary with each proposed research or teaching activity and must be selected appropriately. Please contact the IACUC Office if you have any questions on which appendices are appropriate for your proposed research project.

3. The **Certification of Compliance Assurance** form will be sent to you by the IACUC Senior Administrative Assistant shortly after the receipt of your new IACUC submission. It will be sent with the Protocol title, IACUC number and PI information already completed for you. Please print, READ, sign, and send the document via campus mail to the IACUC Senior Administrative Assistant.

   PI’s are strongly advised to keep a copy of this document for their records, either in print or electronic form, as this represents the **contract** between the PI, VT and the federal government. It also includes instructions for future use or needs for the lifetime of the protocol.

4. **Amendment Forms** must be submitted, approval must be granted and approval letter received by the PI before any changes in personnel, procedures, species or animals numbers can be made in previously approved research or instruction protocols.

5. **Annual Continuing Reviews** are normally completed via an email query form sent by the IACUC Senior Administrative Assistant. PI’s will receive either an email containing basic protocol information to which the PI would reply, completing the
required protocol information, or they will receive an email instructing them to log into a link wherein they will be provided with the same basic protocol information and the PI will complete the required information in an online survey type of format.

Ordinarily, this is all that will be required of the PI. However, if additional information is required, the PI will be sent an “Annual Continuing Review Form – Research” or “Annual Continuing Review Form – Instruction”, as appropriate to the protocol in question.

Form Submission:

With the exception of the signed Certification of Compliance Assurance, of which the signed original is sent to the IACUC Office via campus mail, all forms are to be emailed to the IACUC Office at IACUC@vt.edu as attached Word documents.

Protocol Receipt, Processing and Review:

Protocols are logged into the IACUC database upon receipt and are assigned an IACUC protocol number. Every protocol undergoes two initial independent reviews for completeness and content. A new submission is first sent to the IACUC Administrator or designee for an Administrative Review. The protocol then undergoes a Veterinary Pre-Review by the Attending Veterinarian or other qualified Veterinarian.

PI’s may be contacted by either or both pre-reviewers to provide clarifications, corrections, or with requests to submit missing appendices before IACUC review. These reviews may take 48-72 hours after initial receipt of the protocol. Failure of a PI to respond to questions or queries in a timely manner will result in delays in IACUC review and approval.

Protocols which have successfully passed Administrative and Veterinary Pre-Review are prepared for IACUC Member Review. Each protocol is synopsized and sent in a weekly batch to the members.

The IACUC members are given 6 days to review the protocols and indicate their preference for action on each protocol. These actions include:

1. Hold, and require minor modification; or
2. Allow Designated Member Review (DMR) and approval; or
3. Require full review at a convened IACUC meeting.

NOTE: USDA Pain Category E (see Definitions) protocols MUST be reviewed at a convened meeting of the IACUC and the PI is required to present and defend his/her protocol at the meeting. Protocols will be reviewed at the first available meeting where: a) the protocol has completed all of its pre-reviews; and, b) the PI is available to attend. Meetings
are typically held on the 3rd Thursday of each month, though the meeting schedule may vary due to holidays and other influences. Please plan accordingly when preparing for such a project.

**Member Preference:**

**Hold, and Require Minor Modifications:** the IACUC member forwards his/her questions to the IACUC Senior Administrative Assistant, who then forwards those questions anonymously to the PI and requests a response and/or revisions to the protocol in question. If the response and/or revisions are acceptable to the member(s) who raised the question and requested the hold, the hold will then be lifted. Designated Member Review will then be allowed to take place.

**Allow Designated Member Review and Approval:** the Designated Member Reviewer(s) has/have the authority to conduct the final review on behalf of the entire IACUC. The DMR may also request additional information or revisions from the PI. Once the protocol has been accepted by the DMR Reviewer(s), that/those individuals are empowered to grant approval on behalf of the IACUC. However, the DMR does NOT have the authority to disapprove a protocol, but must return it to the full IACUC for action if they feel they cannot approve the protocol.

**Full Committee Review:** when protocols are sent to the members, as few as one member can call for full IACUC review at a convened meeting. All Category E protocols must be reviewed at a convened meeting and are automatically routed thusly. At the convened meeting with a quorum present, IACUC Members will vote their preference, with a simple majority vote of the members present required. The potential outcomes are:

1. Require modifications (contingent approval); or
2. Approval; or
3. Table; or
4. Disapproval.

**Notification of IACUC Action:**

If a protocol does not receive full approval, the PI will receive an email explaining what action the IACUC took, and what needs to be clarified or corrected before additional review took place.

Upon approval of a protocol, the PI will be sent an electronic copy (PDF) of the official approval letter. They will also receive a Word document version of their complete protocol, including all revisions that occurred through the review process. PI’s are requested to retain both the approval letter and Word version of their protocol. They are also requested to review the protocol in detail with their applicable staff and students, and to PRINT their
protocol and file it in a binder in the lab or otherwise near where the animal work is to occur, to ensure easy staff access to the official version of the protocol.

**NOTE:** Animal studies must **NOT** be started until the PI has received the official IACUC approval letter.

**Protocol Lifespan and Length of Approval:**

Protocols are approved by the IACUC for a 3 (three) year period. PI’s will be required to provide specified information for annual continuing reviews and at the time of the protocol’s expiration or voluntary (early) close-out at the conclusion of the study.

A PI may voluntarily close his/her protocol at any time but a closed protocol may **NOT** be re-opened. Once a protocol is closed in the IACUC database, a new protocol submission must be approved before work with animals on that project may resume.

Annual Continuing reviews are federally mandated and the PI will be sent a query for information as described above. Information required includes but is not limited to:
- Whether the protocol is active (e.g., ongoing or completed/closed)
- The number of animals used to date since the initiation of the study
- Confirmation of the USDA Pain Category, and the numbers of animals used by pain category
- A description of any adverse events affecting animal health and well-being
- Whether any personnel or other changes have occurred outside of the amendment process

Based on the PI’s responses to the initial query, he/she may be asked to complete and submit an Annual Continuing Review Form or be referred to the Post Approval Monitoring Officer for additional follow-up.

**PLEASE NOTE** that the Annual Review is **NOT** a substitution for the Amendment process at Virginia Tech as it is at some institutions. Planned changes must be made via the Amendment process. Unexpected events are required to be reported to the IACUC Office at the earliest convenience of the PI, preferably within 2 business days. See Amendment Submission and Review below.

**In order to avoid interruption of animal use,** PI’s must submit and receive approval for a new protocol PRIOR to the expiration of the original protocol. Animals must **NOT** be used after a protocol has expired or has been voluntarily closed prior to its expiration date. However, unlike human subject research, work with harvested tissue and other data may continue after the expiration of a protocol.
Also, note that it is imperative that PI’s and teaching and research personnel maintain strict tallies of the animals that they have utilized in their teaching and research. PI’s must NOT exceed the number of animals approved on the original submission or any subsequent approved amendments. Failure to do so, resulting in exceeding approved animal numbers, will result in sanctions and, potentially, reporting to the Public Health Service/National Institutes of Health.

Amendment Submission and Review:

Changes in the original IACUC approved protocol **CANNOT** be implemented without IACUC Amendment approval. Amendment forms are available at www.acc.vt.edu, as described elsewhere in this tutorial, and are to be submitted as emailed Word document attachments.

Amendments are reviewed in two categories:

- **Minor Amendments** can undergo administrative review and approval usually in 48-72 hours.
- **Significant Amendments** must be sent to all IACUC members and are usually distributed via the same DMR distribution that full submissions undergo. The IACUC may request a full new submission for significant changes that greatly alter the original research or teaching project. Allow 1-4 weeks for review time, unless the amendment is held over for Full Committee Review (FCR) at the next convened meeting.

Protocols are allowed **three amendments (minor or significant) per protocol**, though amendments that only address personnel changes do not affect this count. However, a change in PI DOES affect the count and is considered a significant amendment.
ANIMAL ACCOUNTING

When submitting the originally proposed protocol, the PI justifies his/her request for animals to be used in the project. This request includes justifying the selection of the species, strain (if applicable), and numbers to be used. When final approval is obtained by the IACUC, the PI is then responsible for monitoring the number and species and/or strain(s) of animals used to avoid exceeding the approved numbers.

If the PI exceeds the total number of animals approved by the IACUC, it is a reportable violation, and the IACUC is required to notify the appropriate federal government oversight office. The IACUC may establish a sanction based on the nature of the violation, including one or more of the following:

- Additional PI training
- Temporary suspension or permanent revocation of the protocol approval
- Temporary suspension or permanent revocation of all of the PI’s active protocols
- Denying privileges to submit any new protocols

When tracking animal usage, certain rules apply. When counting mice, typically only weaned animals are attributed to a protocol. However, if unweaned pups are used experimentally, or their sires or dams were used experimentally to determine effects in offspring, all pups born are to be counted against the protocol. Please see the chart below.

![Animal Accounting Diagram]

Also, strains of mice and rats cannot be added without an approved amendment, but the total numbers of animals approved may be adjusted across all approved strains for that species. For example, if 100 mice each of Strains A, B and C were approved for a total of 300 mice, no other strains may be added without an amendment. However, should the PI realize that Strain A was truly the best choice to continue his work, he may use the remaining...
approved/allowed mice numbers all in Strain A without submitting and receiving amendment approval.

Additional examples of animal accounting include:

1. **Transfer or donation of animals from another PI** – donated or transferred animals will count against the protocol to which they are donated, thus the protocol must be amended to include the additional animals.

2. **Collecting samples from herd or pool animals** – if a PI needs blood or serum monthly from “one” animal, when in fact blood may be obtained from a different animal each month, the total number of animals used should be listed. For instance, if 12 different animals in a herd/colony may be used, the total number of animals listed is to be 12, not 1.

3. **For teaching protocols** = if 6 animals are required each year, and the animals come from a herd or pool where the same animal may or may not be used each year, the total number of animals for the 3 year period of approval will be 18, not 6.

Don’t hesitate to contact the IACUC Office or the IACUC representative for your department if you have any further questions.
ANIMAL DISPOSITION

The disposition of animals to be used in a protocol must be stipulated in the appropriate sections of the protocol submission (e.g., euthanized, transferred, sold). Virginia Tech IACUC policy precludes “adoption” but does allow sale of animals under certain specified conditions.

Animals that will be euthanized on a protocol must be euthanized using methods recommended by the current AVMA Guidelines on Euthanasia. Please see the IACUC website for the link to the current version of this report. Any request to use a method outside of the recommendations of the AVMA Guidelines on Euthanasia must be scientifically justified and references must be provided.

If a physical method of euthanasia is to be used (e.g., cervical dislocation or decapitation) the PI must provide literature citations that clearly demonstrate that the use of chemical euthanasia agents would adversely affect parameters to be studied in animal tissues after euthanasia has been performed.

Where gas anesthetics or carbon dioxide overdose is to be used as the euthanasia method, a secondary method of euthanasia (e.g., cervical dislocation or thoracotomy) will be required to ensure that death has occurred.

Animal carcasses must be disposed of by VT-accepted methods. Please contact the animal facility manager in charge of the facility where your animals will be housed or contact the Attending Veterinarian for guidance.
THE ATTENDING VETERINARIAN

The duties, roles, and responsibilities of the Attending Veterinarian (AV) are defined in the Animal Welfare Act [Title 9 C.F.R., Section 2.33(a) – Attending Veterinarian and Adequate Veterinary Care].

The AV has the authority to ensure that adequate veterinary care is provided at all times, and must have unrestricted access to areas where animals are housed and used in teaching and research.

The AV will consult with PI’s to provide guidance on procedures and drugs to minimize pain and distress. He or she will also assist the PI and research or animal care staff by providing training in humane methods of animal maintenance and experimentation.

The AV is also a voting, *ex officio* member of the VT IACUC.

The AV bears ultimate responsibility for ensuring that treatment is provided and documented in the animal medical records. He or she may request veterinary faculty clinician assistance in animal treatment, however.

If a veterinary faculty clinician is the PI, he or she may request permission to provide clinical treatment to his or her animals, but must maintain all proper documentation and must recognize the ultimate authority of the Attending Veterinarian, on behalf of the IACUC, in determining necessary clinical intervention.

Further, in non-emergency situations, the AV will consult with the PI to ensure that they proposed course of treatment will not adversely affect the outcome of the study; however, in emergencies, the duty of the AV is to protect the health and well-being, and minimize the suffering, of the animal in question.
POST APPROVAL MONITORING

The Post Approval Monitoring (PAM) Officer audits previously approved animal studies. This is required by federal law to ensure continuing compliance after a proposed animal activity is approved by the IACUC. Selection of protocols/studies for PAM audits will be done randomly or “for cause”, e.g., if complaints or concerns are received by the IACUC.

As a best practice, prior to starting a new study, PI’s are strongly encouraged to sit down with their staff and students to review the protocol that is about to begin. The actual IACUC approved protocol document should be reviewed in detail so that the staff are aware of the commitments made to the IACUC by the PI, as this represents a binding contact between the PI, the University and the federal government, which has been stated elsewhere in this tutorial. This heightened level of communication between PI and staff is very significant in improving research quality and enhancing the results of audits. The protocol then needs to be made available in or near the workspace or lab so that it may be referenced as needed. Clear and accurate recordkeeping, especially regarding animal use, breeding and treatment, further improves the quality of research and facilitates PAM audits.

Audits will include, but are not limited to, review of study records and animal health records, observations of animal handling and technical procedures, assurance of accessibility to the approved protocol (e.g., a copy of the actual document as approved by the IACUC) by study personnel, and interviews with the PI and study staff.

At the time of scheduling the PAM appointment, the PI will be instructed as to all relevant animal use data, including animals used to date, health records, etc., to prepare for the meeting, and a brief explanation of the process will also be provided.

Findings and/or recommended corrective action items will be reported by the PAM Officer to the IACUC for review and action as necessary.
ANIMAL USE COMPLAINTS

An overview of the process for reporting concerns about animal use or abuse is provided at the IACUC website – www.acc.vt.edu.

Information signs, with contact information for reporting animal abuse or improper handling or care, are prominently posted in all animal housing facilities. The IACUC has established procedures for investigating and resolving complaints.

All persons making complaints regarding animal use, animal abuse or animal welfare concerns are protected by federal “whistleblower” statutes. Reports may be made anonymously but, because the person making the complaint is federally protected, the IACUC encourages anyone making a complaint to reveal their identity. Doing so greatly facilitates investigation of their complaint or concern and their identity will be protected within the IACUC, if they so request.
Both the IACUC and EHSS have responsibility for ensuring that university staff and students have a safe work environment. For Occupational Health and Safety Education and Training, please go to the IACUC website for more information and a link to the OHS Education and Training website.

Further, information about individual workplace hazards and/or risks is gathered in the IACUC protocol review form and appendices, and in an EHSS questionnaire. Faculty and staff enrollment in the Occupational Health and Safety Monitoring program is optional for most personnel. However, all BL-3/ABL-3 lab personnel and other at-risk personnel must participate in the program.

Completion of the Occupational Health and Safety Monitoring survey is mandatory for all personnel, even those with minimal animal contact. Please contact EHSS and complete the online Occupational Health survey.
ZOONOSES

A zoonosis is any infectious disease (of bacterial, viral, fungal, or parasitic origin) that can be transmitted from wild or domestic animals to humans. The effects of the disease in the human host may range from mild to severe depending on the type of zoonotic agent and the health of the human, and may be more severe in immunosuppressed or immunocompromized individuals.

The IACUC and EHSS will determine the risk of exposure to zoonotic agents based on the species used and the type of contact as described in the protocol review form and appendices. The IACUC and/or EHSS will provide the PI and study personnel with information about likely zoonotic agents and methods to decrease risk of exposure.

Please see the IACUC website for more detailed information on zoonotic agents and Occupational Health and Safety Education and Training – www.acc.vt.edu.

However, the PI bears the ultimate responsibility for ensuring staff (including husbandry staff) know what risks are present, and for ensuring that appropriate personal protective equipment (PPE) is used.
USE OF EXPIRED DRUGS AND PRODUCTS


“The use of expired medical materials such as drugs, fluids, or sutures on… animals is not considered to be acceptable veterinary practice and does not constitute adequate veterinary care as required by the regulations promulgated under the Animal Welfare Act… The facility must either dispose of all such materials or segregate them and in an appropriately labeled, physically separate location from non-expired medical materials… Drugs administered to relieve pain or distress and emergency drugs must not be used beyond their expiration date.”

Thus, expired materials such as sutures or irrigation solutions may be used in acute terminal procedures or in cadavers. However, they must be removed from similar, in-date materials and clearly labeled: “Expired Materials – For Acute Terminal Use Only – Not for use in Survival Surgeries”

NO expired anesthetic or analgesic drugs may be used in terminal or other procedures.
REFERENCES

Guide for the Care and Use of Laboratory Animals

The Guide for the Care and Use of Laboratory Animals is a booklet prepared by the Institute of Laboratory Animal Resources (ILAR). The purpose of the “Guide” is to help institutions address issues that concern the humane care, use and maintenance of laboratory animals. It outlines and references adequate veterinary care, facility environment and housing requirements, personnel qualifications, sanitation standards, surgical and post surgical care, acceptable euthanasia techniques and facility construction guidelines.

The “Guide”, in conjunction with the Animal Welfare Act and other applicable federal, state and local laws, as well as institutional policies, is usually the basis for evaluating the quality of animal care and use programs. Many funding agencies require that animal care and use be conducted in accordance with the standards of the Guide as a condition of providing funding for research projects. In addition, the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC International), an organization that evaluates laboratory animal care and use programs, uses the “Guide” and other documents as a basis to accredit animal care programs.

Copies of the “Guide” are available from the IACUC Office, the TRACSS staff and online (see below).
IACUC Reference Websites:


**USDA Animal Care Policies**, Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture.


**ARENA/OLAW Institutional Animal Care and Use Committee Guidebook**, 2nd Edition 2002:

http://www.nap.edu/catalog.php?record_id=5140

**Policy on Humane Care and Use of Laboratory Animals**, Public Health Service, (August 2002):

http://grants1.nih.gov/grants/olaw/references/phspol.htm

**Guide for the Care and Use of Laboratory Animals**, National Research Council, Washington, D.C.:

http://www.nap.edu/readingroom/books/labrats/

**AVMA Guidelines on Euthanasia**. June 2007:

http://www.avma.org/issues/animal_welfare/euthanasia.pdf

**Animal Welfare Act** as Amended (7 USC, 2131 et. Seq.) - Laws governing transport and other regulations of several species, including dogs and horses:

DEFINITIONS

AAALAC International, Inc
Association for Assessment and Accreditation of Laboratory Animal Care, International, Inc. AAALAC International is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. The College of Veterinary Medicine is currently pursuing AAALAC accreditation.

AALAS
American Association for Laboratory Animal Scientists is a nonprofit membership association that is a primary forum for the exchange of information and expertise in the care and use of laboratory animals. Established in 1950, AALAS provides programs, products, and services to the laboratory animal science community, including online training services, journals and national conferences.

ACC
Animal Care Committee – the name used for VT’s IACUC in years past. See IACUC.

ACUC
Animal Care and Use Committee – another commonly used name for an IACUC. See IACUC.

ALL
AALAS Learning Library is the online training service VT is using as part of meeting its IACUC Core training responsibility for faculty and staff using animals in teaching and research.

Alternatives
Alternatives to or within animal research represent the guiding criteria used extensively in protocol review stemming largely from the concept of the Three R’s in Animal Research - Refinement, Reduction and Replacement (see Three R’s) of animal use that still meets the goals of the research in question. These three R’s, described in a book by Russell and Birch entitled The Principles of Humane Experimental Techniques, are required by federal law to be addressed within each protocol submission.

Amendment
An amendment is a revision to an approved protocol, which is submitted on an amendment form, that must be submitted for review and approval obtained BEFORE any changes in personnel, procedures, species and/or animal numbers can be made in previously approved research or instruction protocols.

Annual/Continuing Reviews
Protocols must be reviewed annually by the IACUC per federal law. Thus, PI’s are required by law to supply animal use numbers, protocol status and related information upon request, usually via an emailed query.

**Approval Letter**
This letter must be received before any animal activity may commence, or, in the case of an amendment, before any changes to an approved animal activity may begin. This includes changes in personnel. It is sent in the form of a PDF-formatted letter that is sent electronically via email to all PI’s on a protocol when a protocol or amendment is approved.

**Attending Veterinarian** (also referred to as University Attending Veterinarian at VT) An ex-officio voting member of the IACUC, this role is required by federal law as the veterinarian responsible for research and instructional animal care and use oversight. This may or may not include clinical responsibilities, depending on the institution. At VT, clinical duties and/or clinical oversight are included in this person’s role. Training and guidance concerning minimizing pain and distress, optimizing protocols and advice on husbandry methods are also key areas where the AV is instrumental in teaching and research procedures.

**AWA**
Animal Welfare Act – the legislative document from which the AWAR derive.

**AWAR**
Animal Welfare Act Regulations – those regulations that USDA/APHIS inspectors utilize when conducting their inspections and that we must adhere to in conducting our everyday business in research and teaching utilizing animals.

**Certification of Compliance Assurance**
The IACUC document wherein the PI signs, attesting to the accuracy and completeness of the submission and that no personnel will participate nor any other changes implemented in the study until and unless approved by the IACUC. This document represents the acknowledgement of the obligations of the PI and contractual relationship between the PI and the IACUC.

**Convened Meeting**
A physical and/or teleconferenced meeting of a quorum of the IACUC, wherein all electronically conferenced persons have full access to all meeting materials. A quorum for VT’s IACUC is defined as 50% of the current membership plus 1.

**DMR Review**
Designated Member Review (also Designated Member Reviewer). Most protocols are approved via this weekly cycle of distribution to the IACUC members. All members of the IACUC are sent protocol synopses each week and given the opportunity to comment on the protocol. If all questions and comments are resolved, the protocol may then be reviewed by the Designated Member Reviewer. This member may not disapprove a protocol. If the DMR chooses not to approve the protocol, it will then be sent to the full IACUC Committee for review at a convened meeting.

FCR Review
Full Committee Review. All Category E protocols and amendments (See USDA Pain Categories) and any protocol or amendment not approved via the DMR process must be reviewed by a quorum of the full Committee at a convened meeting of the IACUC.

IACUC
Institutional Animal Care and Use Committee. This is a federally mandated committee that oversees and approves all teaching and research use of animals. In the case of VT, this includes all vertebrate animals, including those used in food and fiber research.

ILAR
Institute for Laboratory Animal Research – a part of the National Academy of Sciences, this agency “prepares authoritative reports on subjects of importance to the animal care and use community; develops and makes available scientific and technical information on laboratory animals and other biological research resources for the scientific community, institutional animal care and use committees (IACUCs), the federal government, science educators and students, and the public.”

Institutional Official
Also referred to as the I/O, the position is federally defined as the individual at a research facility who is authorized to legally commit on behalf of the research facility that the requirements of the regulations included in Title 9 CFR parts 1, 2, and 3 will be met. At VT, this person is usually the current VP of Research.

IRB
Institutional Review Board. This is the review and protection committee required in any institution conducting research involving human subjects.

LVT
Licensed Veterinary Technician

NIH
National Institutes of Health. This is a federal agency that is responsible for fostering and funding scientific research.
OLAW
Office of Laboratory Animal Welfare. This federal agency is a part of NIH and “provides guidance and interpretation of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, supports educational programs, and monitors compliance with the Policy by Assured institutions and PHS funding components to ensure the humane care and use of animals in PHS-supported research, testing, and training, thereby contributing to the quality of PHS-supported activities.”

ORC
Office of Research Compliance. This is the VT office that oversees IACUC and IRB administrative support activities.

OSP
Office of Sponsored Programs. This is the office within VT that manages grant applications and awards and releases sponsored funding to researchers with approved protocols.

PAM
Post Approval Monitoring – the federal government requires that an institution be aware of the quality of conduct of the protocols that it approves. Any non-compliance, whether found by the institution or by a federal inspector, represents serious risk to the University’s ability to gain and retain federal funding and the privilege to perform animal research or teaching at our institution. Thus, it is prudent to monitor the quality of the animal use in research and teaching performed at VT.

PAM Officer
The person who conducts PAM visits (See PAM) to PI’s, and their labs, using animals in research and instruction. The PAM officer may also be involved in teaching and training of techniques or in the investigation of alleged non-compliance.

PHS
Public Health Service. PHS is one of several governmental bodies that oversee animal research. Because we accept PHS, NIH and similar federal funding, VT falls under the auspices of PHS regulations.

PHS Animal Welfare Assurance
Also referred to as the PHS Assurance. This is a comprehensive document written and submitted by VT to PHS, detailing our animal care and use program. This document represents a contract between VT and PHS and is filed with and approved by OLAW.

Protocol
This document represents a **contract** between the PI and the University, as well as between the University and the federal government. It contains the description of the animal activity or activities to be conducted by a PI in the pursuit of teaching or research utilizing animals. Failure to follow the protocol as submitted may result in significant sanctions to the PI and/or the University. Changes may only be made to the protocol in the form of an approved amendment or in the case of a veterinary medical emergency.

**Proposal**

This term usually applies to the animal use activity description and related research documents provided to accompany a grant application.

**Three R’s**

**Refinements** include the use of analgesia and anesthesia, environmental enrichment for animal housing, better surgical techniques resulting in improved recoveries, etc.

**Reduction** includes better statistical models, the use of self-controls within a study where possible and other innovations that reduce the numbers of animals used in a study.

**Replacement** is typically concerned with using the lowest order of species possible (using a mouse instead of a monkey) or the complete replacement of animal use altogether (computer models, physical/mechanical models such as those used to for teaching suturing, blood draws, injections, etc.). In no way is a researcher expected to use an alternative that does not meet the goals of his/her research. They are, however, expected to examine and utilize alternatives where possible and to account for instances where no alternatives are applicable.

**USDA/APHIS**

United States Department of Agriculture/Animal and Plant Health Inspection Service. This is the regulatory body that inspects our facilities involved in animal care and use in teaching and research. These facilities include animal holding areas (both indoors and outside), surgical suites, laboratories, corridors, etc.

**USDA Pain Categories**

The categories that are used to describe the type of use in which each animal is utilized:

- **Category B**: Breeding or holding animals only; no research conducted.
- **Category C**: Use of procedures that cause no or slight/momentary pain or distress (e.g., observational studies; injection of non-irritating agents; blood collection from peripheral vessels; collection of cells or tissues following euthanasia).
- **Category D**: Use of procedures that would cause more than slight/momentary pain or distress, but are preformed using appropriate anesthetics, analgesics, or tranquillizers to relieve pain (e.g., minor or major surgical procedures [survival or non-survival] performed under anesthesia; collection of cells or tissues prior to euthanasia; painful procedures performed under anesthesia [retro-orbital blood collection in rodents]).
- **Category E**: Use of procedures that cause more than slight/momentary pain or distress, but that cannot be performed using anesthetics, analgesics, or tranquillizers without
adversely affecting the study (e.g., toxicity and lethal disease studies in which the animals are allowed to die without intervention and mortality is the endpoint). Mechanical restraint may, depending upon duration and type of restraint, be considered a category "E" procedure. **Approval to conduct a Category E study requires detailed justification and must be reviewed at a convened meeting of the IACUC where the PI presents and defends his/her submission.**

**UAV** – See Attending Veterinarian

**VMO**
Veterinary Medical Officer – the term for the USDA inspector who inspects teaching and research facilities. This person’s qualifications almost always include a DVM or its equivalent.

**Whistle-Blower Policy**
Also referred to as the improper animal care or abuse of animals reporting mechanism, this policy is federally mandated, as are the signs in animal use and holding areas alerting personnel as to how to make such a report if abuse is witnessed. Federal law protects the person making the report from retribution, thus anonymous reports are discouraged where possible as they make investigation very difficult.

**Zoonoses**
Plural of “Zoonosis”.

**Zoonosis**
A zoonosis is any infectious disease (of bacterial, viral, fungal, or parasitic origin) that can be transmitted from wild or domestic animals to humans. The effects of the disease in the human host may range from mild to severe depending on the type of zoonotic agent and the health of the human, and may be more severe in immunosuppressed or immunocompromized individuals. Also referred to as a “zoonotic disease” or “zoonotic agent”.
FINAL QUIZ

When you have completed studying this course, please proceed to the link below to take a short 10 question quiz.

https://secure.research.vt.edu/orc_cert/?cert=iacuc_training