AVERTIN & PENTOBARBITAL
Special Campus-Wide Exemptions

In January of 2012, the NIH issued instructions that institutions receiving federal funds (PHS Assured Institutions) must abide by the guidance found in the 8th Edition of The Guide for the Care & Use of Laboratory Animals. In March 2012, the NIH/OLAW provided a webinar wherein they noted specific concerns with certain uses of non-pharmacological agents (avertin) and certain pharmacological agents that are exceedingly expensive (pentobarbital). In response to the NIH/OLAW positions, the Duke IACUC has determined the following:

♦ Avertin (or Tribromoethanol) is appropriate for short term procedures in mice, especially surgical procedures. It’s best used in situations where it will be given only on a single occasion. The preparation and use of this anesthetic must be:
  ◆ Scientifically necessary,
  ◆ Appropriately justified, and
  ◆ Approved by the IACUC.
In making its decision the IACUC must consider the side effects, stability, storage requirements and other considerations associated with the preparation of this agent (the PI must provide this information for IACUC consideration).

♦ Pentobarbital (pharmaceutical grade) current costs up to $1000.00 per 50 ml bottle. For certain applications and certain studies, scientific necessity requires continued use of this barbiturate. The IACUC will consider and may approve requests to use a non-pharmaceutical grade of pentobarbital under the following circumstances:
  ◆ Scientifically necessary,
  ◆ Appropriately justified,
  ◆ Prepared from a reagent or analytical-grade powder.
In making its decision the IACUC must consider the side effects, stability, storage requirements and other considerations associated with the preparation of this agent (the PI must provide this information for IACUC consideration).

See the Policy for Non-Pharmaceutical Grade Substances for more information.

OESO and OAWA have worked together to update the Section H (Hazardous Agent Use) form used for animal protocol submissions. It is now a requirement that ALL hazardous agent use be documented in the Section H (including use of formalin or paraformaldehyde for fixing tissue). This new form has instructions that outline exactly what is needed to achieve protocol clearance from OESO. Required Standard Operating Procedures (SOPs) should be appended to the protocol submission (sent to iacuc@duke.edu) for OESO review. There is a new requirement that the SOP for Handling Animals Dosed with Toxic Chemicals must be completed and submitted for hazardous chemical agents used in animals. The updated version of this SOP has a place for protocol personnel to sign and date that they have read the requirements. Submitting this completed animal handling SOP ensures that the door sign is completed correctly and animal caretakers are made aware of the hazardous agents used at their facility so they can properly protect themselves from exposure when changing and dumping cages.

Please be sure to download the updated Section H form (version date 2012 07) instead of using the older version. This will help your protocol review and approval go smoothly and quickly.

As always, if you have questions about OESO clearance and animal protocol review of hazardous agents, please contact OESO at 919-684-2794.
APPLICATIONS FOR THE NEXT RESEARCH ANIMAL COORDINATOR CERTIFICATION (RACC) COURSE NOW BEING ACCEPTED

The Duke Animal Care & Use Program offers a training and certification program for individuals wishing to serve as their laboratory ‘go-to’ person. Referred to as the Research Animal Coordinator Certification (RACC) program, individuals who participate in this program receive specific and detailed training concerning animal care and use regulations, requirements, and policies at Duke - the goal of which is to facilitate research, enhance understanding, and minimize non-compliance.

Those who achieve certification may be designated by their Principal Investigator (PI) as the laboratory coordinator for all animal activities and may provide in-lab guidance regarding animal care & use at Duke (serve as an extension of the IACUC and veterinary staff).

The RACC program benefits the PI and research laboratory (smoother research protocol application, more efficient review/approval, and decreased risk of non-compliance issues) while also benefiting the RACC candidate (enhancing their value to the research team, improving personal research skills, enhancing their knowledge of how to ‘get things done’).

The RACC program is voluntary, and offered at no-cost. Managed by the Office of Animal Welfare Assurance (OAWA) with significant contributions from the Division of Laboratory Animal Resources (DLAR) and the Institutional Animal Care & Use Committee (IACUC), the RACC program uses a multi-modal educational approach (e.g., lectures, web-modules, meetings, one-on-one discussion, and hands-on learning).

Not sure if you want to apply and become a RAC? Send an email to Bill Wade (w.wade@duke.edu) and he can arrange for you to meet one of this very select group of campus professionals. Applications are available on the Duke Animal Program Website.

You'll find a complete description of the course requirements and curriculum, and upon successful completion of the course, your receive the Duke RAC lapel pin, the Duke RAC Certificate; and you will become a more important and useful member of your research laboratory team. Submit your application to Bill Wade. All applications must be endorsed by your Principal Investigator.

FBR NEWS

Paul McKellips, FBR Executive VP

The public opinion tracking poll for May is now in and 66.7% of the American public SUPPORTS the humane, responsible, and ethical use of animals in research.

I was so cautious, in fact, with our five consecutive months of progress, that I asked Zogby to double the polling size so that we could further reduce the margin of error (Poll Margin of error: +/- 1.5%). In the latest poll (May 2012) 4,567 adults were surveyed. Here are some of the splits:

⇒ MEN (2,196 polled): 76.5% support
⇒ WOMEN (2,331): 57.9% support
⇒ EAST (1,000): 64.5% support
⇒ SOUTH (1,182): 70.2% support
⇒ GREAT LAKES (1,364): 69.1% support
⇒ WEST (1,000): 62.2% support
⇒ DEMOCRATS (1,735): 57.9% support
⇒ REPUBLICANS (1,507): 74.0% support
⇒ INDEPENDENTS (1,279): 71.7% support

NIH Clarification of OLAW Positions Statements On the New Guide Is Published in Federal Register

As previously announced in the NIH Guide to Grants and Contracts and reported by the NABR Update, the NIH Office for Laboratory Animal Welfare (OLAW) announced today in the Federal Register (77FR 38073) it has clarified its position statements regarding implementation of the Guide for the Care and Use of Laboratory Animals. In response to public comments received, NIH has clarified the following Position Statements: (1) Cost, (2) Housing, (2a) Nonhuman Primate Housing, (2c) Rodent Housing, and (3) Non-Pharmaceutical-Grade Substances. A summary of the changes in the Position Statements and an archive of the original version are available. A copy of the 8th Edition of the Guide may be downloaded at the OLAW website.
Senate Appropriations Report Supports Several NIH Actions Related to Research Animals

Several subjects related to research animals are included in Senate Report 112-176, the report accompanying the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act for 2013, S. 3295. The Senate Committee on Appropriations commended the National Institutes of Health (NIH) for adopting the Institute of Medicine’s (IOM) recommendations regarding research involving chimpanzees and for moving to end the use by grant recipients of dogs and cats from USDA-licensed Class B (random source) animal dealers.

The Committee indicated support for National Primate Research Centers (NPRCs) and said it "expects they will receive the same level of attention in the OD [Office of the Director] that they received in the now-dissolved National Center for Research Resources." Lastly, the Committee supported NIH’s leadership role in the Tox21 program, a collaborative effort with the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) to adopt advanced molecular biological and computational methods in lieu of animal toxicity tests for conducting chemical risk assessments. The Committee asks NIH to provide a report on FY 2012 and 2013 funding for Tox21 activities with the FY 2014 congressional budget justification.

NOW AVAILABLE

US Navy Captain “Camp” Campbell, a trauma surgeon and former SEAL, is dispatched to a remote American base on the Afghanistan – Pakistan border to investigate the abduction of an American Army doctor. The US Army Battalion Surgeon had discovered a small outbreak of tularemia – rabbit fever – before he was kidnapped by Taliban loyalists.

Recovering from life-threatening wounds received on a covert mission to Yemen, Lieutenant Colonel Leslie Raines is assigned to the BSL-4 facility at Fort Detrick where she works on a vaccine resistant strain of tularemia that could be used as an international bio-weapon.

Camp joins US Army Operation Detachment Alpha Team on a covert mission up and over the Hindu Kush mountains and into the volatile and lawless North Waziristan region in search of the abducted physician. What the team discovers in a third world laboratory and rudimentary surgical suite, takes Camp and Raines on an international, page-turning race against time.

Throw out the rationalist’s cost-benefit analysis of war. In this tight, tense, and politically fraught thriller with apocalyptic religious overtones, will state-sponsored bio-warfare take the world to the edge of Armageddon?

JERICHO 3 is an international bioterrorism thriller so frighteningly realistic the storyline could very well be ripped from tomorrow morning’s newspaper headlines.

Would terrorists and state sponsors of bio-weapons really risk mutual annihilation to kill millions of innocent people? Can the world’s best and brightest scientists cook the same bio-death recipe in time to conduct the animal research necessary to develop adequate vaccines and antibiotics? Would the government of Iran truly sanction the destruction of other countries and risk their own demise in order to usher in the coming of the Islamic messiah? Will Western diplomats ever fully comprehend the radical agenda? Can anything prevent Jericho 3?
ACADEMY OF SRUGICAL RESEARCH OFFERS CERTIFICATION FOR SURGICAL SPECIALIST

In 1982, forward-thinking scientists the Academy of Surgical Research, which among other presentations to society, also offers certification in surgery for non-veterinarians. The Duke IACUC accepts ASR certification as evidence of skills qualifications. The Academy offers three types of surgical certification:

⇒ Surgical Research Anesthetist (SRA) Certification  
⇒ Surgical Research Technician (SRT) Certification  
⇒ Surgical Research Specialist (SRS) Certification

The minimum requirements for each certification are detailed below. Candidates should include all of the cases they perform in their log in order to accurately outline their relevant experience. The log reinforces the importance of monitoring outcomes as a life-long responsibility of surgeons and anesthetists performing aseptic survival surgery. It is the responsibility of the candidates’ organization to review the log and attest to its accuracy.

The cases reflected in the log must occur over a 12 month period, with no more than three years transpiring between the oldest case and the date of application. In certain cases, exceptions may be made at the discretion of the Certification Committee and the Academy’s President.

Surgical Research Anesthetist (SRA) Certification:

- **Case Log:** The case logs for the SRA will consist of a minimum of 30 anesthetic cases, with no more than 15 in any one species. Acceptable cases must be longer than 30 minutes of surgical duration, have had the applicant present from induction through recovery, have the applicant primarily acting as the anesthetist and have a minimum of monitoring to include heart rate, respiratory rate, body temperature, and at least one of the following parameters: blood pressure, SaO2, or capnography. At least two different species must be included. Rodents may be included provided that the above monitoring was performed with the applicant present. Applicant may not deliver the patient to the surgeon and then leave the room. Acceptable survival surgical procedures are required for the SRA logs and narratives, which involves a minimum of 72 hours of survival post-surgery before euthanasia. An exception may be made for complex acute procedures which require the applicant to adhere to a rigorous anesthetic management protocol with multiple drugs being administered to maintain the patient (these exceptions will be made at the discretion of the certification committee on a case by case basis).

- **Narratives:** The applicant must submit two narratives which detail two of the cases from the applicant’s anesthesia log. Each narrative should comprehensively describe all aspects of the anesthetic protocol, including the following:
  - Drug Regimens including doses, routes of administration and timing related to the surgical procedure (prior to surgery, during the procedure, etc.) for pre-anesthetic, anesthetic, analgesic, and antibiotic drugs.
  - Justification for the anesthetic regimen used.
  - The methods used to monitor the animal’s condition and anesthetic depth pre-operatively, intra-operatively, and immediately post-operatively.
  - A description of the animal’s condition during the procedure in linear format including what adjustments were made in drug administration, the reasons for these changes, and the results.
  - Animal preparation for surgery including areas clipped, surgical positioning, antiseptic prep regimen, and fluid therapy.
  - An overall assessment of the efficacy of the anesthetic protocol for the animal and what changes, if any, were made based on the results.
  - Any complications which occurred during the anesthetic period and how they were addressed.
  - Post-operative monitoring and pain assessment including species appropriate signs of pain and distress and duration of monitoring including follow-up procedures and care.

Surgical Research Technician (SRT) Certification:

- **Case Log:**
  - The SRT case log will include a minimum of 12 survival, aseptically performed procedures defined as “minor” surgical procedures. At least two different procedures must be included. Non-survival procedures should be included to help outline the candidate’s experience, but won’t count towards the required number of cases.
  - Minor procedures include: peripheral vascular cannulation, vascular access port implantation, castration, large reservoir subcutaneous pump implantation, and/or subcutaneous radio-telemetry device placement, etc.
  - Examples of procedures that do not qualify as minor procedures are implantation of subcutaneous ID chips or any procedure using an injectable type device.
  - Acting as a sterile assistant on major procedures may be accepted as long as the duties were significant (including at a minimum substantial dissection and closure) and are adequately described in the log.
  - The case log must include the type of procedure, the date of the procedure, the species and sex involved, a record of any complications and their treatment, whether the procedure was performed
aseptically, the final disposition of the animal, and the candidate’s role (primary surgeon or assistant). If the candidate’s role was as an assistant, the duties performed need to be described.

- **Narratives**: The applicant must submit two narratives of cases represented in the case log. Narratives should comprehensively describe all aspects of the procedure, including:
  
  - Drug regimens, including doses, routes of administration and timing related to the surgical procedure (prior, during, or after the procedure) for pre-anesthetic, analgesic, and antibiotic drugs
  
  - Justification for the regimen itself
  
  - The methods used to monitor the animal’s condition and anesthetic depth pre-operatively, intra-operatively, and immediately post-operatively
  
  - Animal preparation for surgery including areas clipped, surgical positioning, and the antiseptic prep regimen
  
  - Detailed description of the surgical technique including incision creation, tissue dissection, identification of the tissues encountered, methods of hemostasis used, identification of critical instruments used, and closure techniques (suture patterns and materials used)
  
  - Acceptable survival surgical procedures involve a minimum of 72 hours of survival post-surgery before euthanasia
  
  - Post-operative monitoring and pain assessment including species appropriate signs of pain and distress and duration of monitoring and follow-up treatments

**Surgical Research Specialist (SRS) Certification:**

- **Case Log:**
  
  - The SRS case log must have a minimum of 12 major, survival procedures in which the applicant acted as primary surgeon. There must be at least two different procedures, in two different species, other than a rodent. If procedures are performed only in rodents, a minimum of 24 cases must be included in the log with 4 different procedures being performed.
  
  - Major procedures include those that enter a body cavity, vascular anastomosis, significant orthopedic surgery, or involve significant CNS manipulation such as intra-thecal cannulation and nerve anastomosis.
  
  - The case log must include the type of procedure, the date of the procedure, the species and sex involved, a record of any complications and their treatment, whether the procedure was performed aseptically, the final disposition of the animal, and the candidate’s role. If the animal is transferred to other personnel post-surgically, this observation may be included in lieu of reporting the final disposition of the animal.

- **Acceptable survival surgical procedures involve a minimum of 72 hours of survival post-surgery before euthanasia.**

- **Non-survival procedures should be included to help outline the candidate’s experience, but will not count towards the required total.**

- **Narrative**: The narrative requirements for the SRS certification are the same as for the SRT certification.

For more information, contact the Academy of Surgical Research at: 7500 Flying Cloud Drive, Suite 900 | Eden Prairie, MN 55344 | Tel: 952.253.6240

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**FALL 2012 IACUC SEMI-ANNUAL SITE VISIT SCHEDULE**

Make a note of the date for your facility. Inspections will take place on Thursday afternoons from 1:00 to 4:00 PM.

- August 2, 2012: LSRC – SANDS
- August 9, 2012: GSRB2
- August 16, 2012: BRYAN – NANALINE DUKE – VSH CARY
- August 30, 2012: JONES – RP 2, 3 & 4 – GSRB2 ANNEX – ENGINEERING – GSRB1
- September 6, 2012: MARINE LAB – MUSEUM OF LIFE & SCIENCE
- September 13, 2012: CARL – DLAR FARM – EYE CENTER – INDY PARK
- September 20: CCIF
- October 4, 2012: FRENCH FAMILY SCIENCE – BIOLOGICAL SCIENCE – FOSTER ST.
- October 11, 2012: DUKE SOUTH – GHRB – CIEMAS (FITZPATRICK)
- October 18, 2012: VIVARIUM – MSRB
- November 1, 2012: LEMUR CENTER – MSRB2 – ECOTOX FACILITY

Note: If you had a RAC, you could have them to a pre-inspection for you so you
The Benefits of AAALAC International Accreditation

More than 850 institutions in 36 countries around the world have earned AAALAC International accreditation. Here are a few of the reasons why so many biomedical and agricultural research programs chose to participate in AAALAC’s program …

It represents quality

Organizations and companies look for ways to communicate their commitment to excellence. In the scientific community, AAALAC International accreditation shows that an institution is serious about setting, achieving and maintaining high standards for animal care and use and committed to animal welfare in science. AAALAC International offers the only international accreditation for animal care and use programs, and it has become recognized around the world as a sign of quality and sound science.

It promotes scientific validity

When research involves animals, reliable scientific results depend on superior animal care. AAALAC International accreditation engages scientists, veterinarians, managers and administrators in an independent, rigorous assessment of their institution’s animal program—an assessment that ultimately results in improved animal welfare and better research practices and outcomes.

It provides assurance in a global marketplace

Today it’s common for research institutions to partner or contract with other research entities around the world. Because laws and regulations related to animal research vary widely from country to country, AAALAC International accreditation can be used worldwide as a way to gauge the quality of a particular program, harmonize animal care and use practices, and provide assurance to diverse stakeholders.

It’s a recruiting tool

AAALAC International accredited institutions can use their accreditation as a recruiting tool to attract the best and brightest researchers and professors. Talented professionals look for high quality programs to support their research. Accreditation assures potential employees that the institution is dedicated to achieving the highest standards for animal care and use.

It demonstrates accountability

In today’s world, companies and organizations are held to very high levels of accountability—by their own constituents and the general public. Although animal research is a controversial issue for some, most people support biomedical research if it’s conducted in a humane manner. Accreditation through AAALAC International is voluntary and demonstrates a willingness to go above and beyond the minimums required by law. It tells the public and other stakeholders that the institution is committed to the responsible care and use of animals in science.
The Benefits of AAALAC International Accreditation

It advances animal welfare and promotes the “Three Rs”

AAALAC International accreditation helps institutions enhance their stewardship of the animals they use in research, teaching and testing. Participation also helps institutions focus on, and demonstrate, their support for the tenets of “Three Rs” of animal research: “Reduce, Refine and Replace.”

It provides a confidential peer-review

AAALAC accreditation requires an institution to first perform its own self-evaluation (an extremely valuable exercise for any institution to undertake). Next, a team of highly qualified AAALAC representatives provides an in-depth, confidential, on-site evaluation of the institution’s animal care and use program. This independent peer-review ensures that the institution’s program is meeting AAALAC International standards.

It stimulates continuous improvement

When an institution participates in the AAALAC accreditation program, it’s committing to a process that stimulates continuous improvement. Earning and maintaining accreditation keeps an institution aware of, and engaged in, current best practices. Accreditation is a true commitment to humane animal care and use and shows the world that an institution is serious about ensuring animal well-being and conducting good science.

It instills a sense of pride and teamwork among animal care personnel

Earning and maintaining AAALAC International accreditation is a great achievement that can instill a sense of tremendous pride throughout all levels of an organization. In particular, it can be an immensely satisfying accomplishment for the animal care technicians, custodians, and others who provide much of the day-to-day care for an institution’s animals. The process of earning and maintaining accreditation is often a valuable team-building experience for the entire animal care and use staff.

What people say about the AAALAC International accreditation program

(Following are comments from AAALAC’s most recent survey of institutions participating in the accreditation program…)

“We always learn something new that helps our program as a result of an AAALAC site visit.”

“AAALAC is a valuable resource for information and support. AAALAC site visits have been essential in gaining administrative support for needed improvements in our program during times of fiscal constraint.”

“It’s very helpful to have an objective outside observer review our operations and programs and let us know where we need to strengthen our procedures.”

“AAALAC is a ‘Good Housekeeping’ seal of approval and has public relations value.”

“Our institution has found AAALAC site visits helpful and informative. We appreciate your suggestions and strive to implement all of them. It’s our mission to constantly be improving our laboratory animal program and AAALAC has provided sound guidance.”

“We acted on many of AAALAC’s suggestions. Very helpful. Thank you!”

“This was my first site visit and it was a very helpful, professional, and value-added experience for our program.”

“Honestly speaking, even though we get a little anxious, we look forward to your visits.”

“The assistance from AAALAC in providing clear statements of the importance of ethics, care, and compliance in working with animals is extremely valuable. We appreciate you!”

“AAALAC is a valuable resource and we get better after every AAALAC site visit.”

“I view AAALAC as a partner in research!”