



# ANIMAL TRACKS



A newsletter for the Duke research community

April 2007

<http://www.duhs.duke.edu>



## Protocol Amendment Review Processes

The Duke Institutional Animal Care & Use Committee (IACUC) uses a 'triage' system of managing applications for protocol amendments. While there is only a single 'form' (available on the animal program web site) for submitting any amendment, there are three different methods of amendment review (Minor, Minor with Veterinary Review, Significant) which are determined based upon IACUC approved criteria, as defined in federal law and policy.

Characteristics of these review modalities are:

- A. Minor Amendments:** These are amendments that DO NOT change the animal's perspective of the approved activity. Examples include:
- i. Transfer of animals to another protocol where animals (same stock / strain) are already approved on that study.
  - ii. Addition or deletion of personnel.
  - iii. Adding or changing the site of animal procedures (less than 12 hours).
  - iv. Change in Euthanasia procedures (AVMA Approved Methods only).

Minor amendment are generally processed (and usually approved) within 3 business days of receipt by OAWA. Issues that could delay approval include:

- i. Personnel have not completed OESO or EH requirements.
- ii. Missing 'Personnel Qualifications Form'
- iii. Poorly described euthanasia procedures.

When approved, an approval memo is be sent by Email to the Principal Investigator of record. DO NOT proceed with the requested amendment until you have received the approval memo.

**(NOTE: See 'Q&A' on Page 3 for more details on approvals).**

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## Ergonomics in the Laboratory

The word "ergonomic" comes from the Greek "ergon" meaning "work" and "nomos" meaning "law." Ergonomics is the study of the body at work and the body's interaction with it's work environment. The proper application of ergonomics must take into account biomechanics, the study of body forces and movement and anthropometry, or the study of human body measurements especially on a comparative basis. The proper application of ergonomics can alleviate worker discomfort, improve productivity, reduce absenteeism, and negate medical costs. Through applied product engineering, ergonomics provides equipment adapted to the biomechanics and anthropometrics of the human, instead of the human having to improperly adapt to the product.

Only in recent years has ergonomics moved to the forefront of public awareness. While the majority of study conducted regarding ergonomics has been in the office setting, work in the laboratory is also a source of repetitive motion injury, thereby providing opportunity for workstation improvement as well. Repetitive tasks are inherent to laboratory research. Most labs are typically designed to support production, research and sterility, not worker comfort. Although the National Institutes of Health and OSHA have recognized lab work as an occupation with risk for musculoskeletal disorders and repetitive stress injuries (RSIs), ergonomics in the biomedical research laboratory has not received the level of attention conferred to non-laboratory settings. As one laboratory discovered, researchers who use biological safety cabinets and fume hoods are at risk for RSIs. Immunex Corp. in Seattle, WA, found five risk factors observed in labs: contact stress, force, repetitiveness, static loading, and vibration.

Poor posture and positioning were the most common problem observed. Work at the biosafety cabinets required researchers to hold their heads and arms in a forward position with shoulders rounded forward. Such a static posture can compromise the vascular supply, compress nerves in the arms and increase muscle stress and strain.

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## Foundation for Biomedical Research

The Foundation for Biomedical Research provide free resources on their web site <http://www.fbresearch.org/Education/index.htm> Some of the available items include:

<b>Brochures</b> <a href="#">Facts vs Myths (pdf)</a> <a href="#">Proud Achievements of Animal Research (pdf)</a> <a href="#">The Importance of Being a Mouse (pdf)</a>	<b>Species Sheets</b> <a href="#">Rats and Mice (pdf)</a> <a href="#">Dogs and Cats (pdf)</a> <a href="#">Non-Human Primates (pdf)</a> <a href="#">Other Species (pdf)</a>
<b>Opinions About Animal Research</b> <a href="#">Scientists</a> <a href="#">Religions</a> <a href="#">Organizations</a> <a href="#">Opponents</a>	<b>Other Resources</b> <a href="#">AIDS and Animal Research</a> <a href="#">Facts About Animal Research</a> <a href="#">Nobel Prizes</a> <a href="#">Animal Research 101</a> <a href="#">Facts About Vaccines</a> <a href="#">Kids for Research</a> <a href="#">Links for further research</a>

## What is AMP?

Americans for Medical Progress (AMP) protects society's investment in research by nurturing public understanding of and support for the humane, necessary and valuable use of animals in medicine. Threats by animal rights extremists hurt medical progress. AMP provides accurate and incisive information to foster a balanced public debate on the animal research issue, ensuring that among the voices heard are those whose lives have been touched by research and those who work in the field. Through various specialty publications, outreach initiatives and the media, AMP informs the public of the facts of animal-based research. AMP also distributes timely and relevant news, information and analysis about animal rights extremism to the research community through its news service. For more information on AMP, visit their website at [http://www.amprogress.org/site/c.jrLUKOPDLof/b.913145/k.4502/Americans\\_for\\_Medical\\_Progress.htm](http://www.amprogress.org/site/c.jrLUKOPDLof/b.913145/k.4502/Americans_for_Medical_Progress.htm)

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## Kids 4 Research

A great place for kids is "Kids 4 Research!" The "Kids-4-Research" web site provides information to students, teachers, and parents on responsible laboratory animal care and use in biomedical research, testing, and education. The site also provides information on the benefits of such research to animals, humans, and the environment. Visit the site at: <http://www.kids4research.org/>

## North Carolina Biomedical Research (NCABR)

Founded in 1989 by North Carolina's leading bioscience research institutions (including Duke), the North Carolina Association for Biomedical Research (NCABR) is the only organization in the state dedicated to advancing all North Carolinians' appreciation for the remarkable benefits of bioscience research and careers. As a statewide nonprofit organization, NCABR's members include academia, industry, government, hospitals, nonprofit research, voluntary health and other nonprofit organizations, as well as the general public. NCABR plays a leading role in North Carolina and the nation by providing objective, timely and authoritative advice and information to students and educators, representatives from government and the media, as well as members of the research community and the general public.

Since 1989, NCABR has launched innovative science education outreach programs and has designed a variety of bioscience education and career-related publications — many of which are the first of their kind in the country and are now used nationally. NCABR's ongoing efforts to promote public understanding of biomedical research were recognized in 1999 when Research America, a national nonprofit public education and advocacy alliance of 450 research organizations, honored NCABR with its prestigious national award for "An Organization that has Distinguished Itself By Its Advocacy" for bioscience research. NCABR received this award in a ceremony in the United States Senate along with NBC news anchor Katie Couric and former Oregon Senator and Governor Mark Hatfield.

To date, more than 2,000 North Carolina K-12 teachers have participated in NCABR's science education programs, more than a thousand North Carolinians have attended an NCABR public forum to debate biomedical research issues, and dozens of members of the North Carolina and national media have attended an NCABR science journalism program. For more information about our own biomedical research organization, visit their website at: <http://www.ncabr.org/>

## Upcoming Events

April 5	SC meeting
April 9	New protocol deadline, SC deadline
April 19	SC meeting
April 23	SC deadline
April 26	IACUC meeting
May 3	SC deadline
May 7	New protocol deadline, SC deadline

SC= Significant change

# New Technology

## The New LifeShirt Preclinical Delivers Better, Non-invasive, Real-time, Life-sign Monitoring

View in **real-time**, high quality physiologic data from unrestrained, unstressed and uninstrumented animals and be able to perform detailed analyses offline.

- The most accurate and meaningful measurement of respiration
- Continuous data in freely moving subjects up to 24 hours
- Monitor up to 16 animals in one room
- Reduction in labor and surgery costs
- Less stress leading to accurate results
- Use VivoMonitor software or integrate easily with other software analysis packages
- Flexible room setup with a portable receiver cart

Want to learn more about the New LifeShirt Preclinical System? Contact Jeremie Braun at 805-275-5815 or email [info@vivometrics.com](mailto:info@vivometrics.com)

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**B. Minor Amendments with veterinary approval:** These are amendments that will (or have a potential of) affecting the animal's well being, welfare, or the procedural outcome. Examples of these include:

- *Change in anesthetic drug regimens.*
- *Change in analgesic drug regimens.*
- *Addition of surgery or procedure that is less invasive than already on the approved protocol, or would result in a decreased proportion of expected animal deaths.*
- *Changes in animal care and monitoring practices.*
- *Change in humane endpoints*
- *Addition of sample collection times.*
- *A small increase in animal numbers.*
- *Addition of a repetition of an already approved experiment.*
- *Addition of noninvasive sampling/analysis.*
- *Addition of another strain/stock of the same animal species.*

Minor amendments are generally processed (and usually approved) within 10 business days of receipt by OAWA. Issues that commonly delay approval include: Personnel have not completed OESO or EH requirements; Missing or unclear description of the proposed changes.

**When approved, an approval memo is be sent by Email to the PI of record. DO NOT proceed with the requested amendment until you have received the approval memo.**

**C. Significant Amendments:** *These amendments include those items that are defined in federal regulations, policies, or rules or have clear significant impact upon the*

*animal that was not approved in the original protocol. Examples of these include:*

- *Species addition.*
- *Housing for greater than 12 hours in the lab.*
- *Change in non-survival to survival surgery.*
- *An increased invasiveness of a procedure.*
- *Large animal death loss.*
- *Greater duration of pain, discomfort, or distress.*
- *Addition of a hazardous agents (as defined by OESO).*
- *Change of the Principal Investigator (PI).*
- *Addition of neuromuscular blocking agents.*
- *Change in euthanasia procedures (AVMA Conditional or Not Acceptable procedures).*

Significant amendments are generally processed and reviewed within 14 days of receipt (the IACUC Subcommittee on Significant Amendments meets on the 1<sup>st</sup> and 3<sup>rd</sup> weeks of the month). Issues that commonly delay approval generally involve missing or unclear description of the proposed changes.

**When approved, an approval memo is be sent by Email to the PI of record. DO NOT proceed with the requested amendment until you have received the approval memo.**

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(Continued from Page 1 ... Ergonomics in the Laboratory)

This hunched-forward position is further exaggerated when the feet are placed on the ring-style footrest common to many lab stools. Proper posture is the "neutral" position, or the position that requires the least amount of muscle force and allows maximum room for blood flow. Immunex found that the use of an industrial-height footstool allows technicians to achieve the best possible posture and position at the static biological safety cabinet. Providing an adjustable lab stool with enhanced lumbar support was also an important improvement.

Failure to outfit and setup a laboratory workstation properly can encourage the development of RSIs. The proper chair adjusted to the correct settings and tables and work surfaces set at a comfortable height can improve worker comfort and productivity. In addition, attention to environmental and user/equipment interface factors will create the most ideal "ergonomic" work situation.

Conclusion: Productivity in the laboratory environment can be improved through an understanding of ergonomics. The proper application of ergonomics in the biological safety cabinet design may alleviate worker discomfort, improve productivity, reduce absenteeism, and negate medical costs. For a full report on ergonomics in the design and use of biological safety cabinets, contact Baker at 800-992-2537 or online at <http://www.bakerco.com>.

### References

\* Office Products and Services Guide, "Applying Ergonomics," OPS website, [www.asiapages.com.sg/ops/text/ergonom.htm](http://www.asiapages.com.sg/ops/text/ergonom.htm), p.1

\* IAC Industries, Brea, Calif, Ergonomics User Manual, p.2

**Ed Note: Text from The Baker Company, P. O. Drawer E, Sanford, ME 04073; 800-992-2537**

## Q & A

**Question:** My protocol is about to lapse due to circumstances beyond our control. It has taken us a long time to breed and develop our animals for research. Is there any way we can keep from euthanizing our animals?

**Answer:** The animal program does have an 'Animal Holding Protocol' for certain selected purposes. Eligibility for the holding protocol is determined on a case-by-case basis. Situations which may allow for use of the holding protocols include:

- A non-compliance situation where the IACUC has taken the animals into receivership;
- Animals remaining when a protocol is inactive (or terminated);
- Animals on a protocol under investigation for potential issues of non-compliance where the welfare or well-being of the animals is in question;
- New investigators coming to Duke that require immediate housing of their animals but do not have an approved Duke protocol presently; or
- Investigators that are leaving Duke and do not have the necessary approvals for transfer to the new institution.

For more information, see the IACUC policy on the animal program website or call the DLAR @ 681-6792.

**Question:** I heard there is a new process that requires registration of transgenic mice. Is this true? How do I register?

**Answer:** The need to register creation of transgenic mice with the IBC is an NIH requirement of their recombinant DNA Guidelines. In fact, the Duke transgenic animal facility will not allow such work unless there is an IBC approval. All of the information about the Guidelines, and how to comply with these at Duke are found on the Lab Safety website: <http://www.safety.duke.edu/LabSafety/DNA.asp>. The only form required for transgenics is the rDNA registration form (linked on this website), unless you are using a viral vector. The rDNA form is 2 pages. You can send it to me at this e-mail address or at the biosafety e-mail indicated on the form. Once I receive this, we can sign off on the protocol. I'll then take it to the IBC next week for review and approval. You will then get a status report back. Information about the IBC, the need to register recombinant DNA protocols, and the above links are included in the on-line Laboratory Safety Training that is required annually of all lab personnel. For more information, contact Debra Hunt at OESO [[hunt0009@mc.duke.edu](mailto:hunt0009@mc.duke.edu)].

**Question:** I am not entirely clear on my responsibilities under PHS Grant Policy. Is there a document or resources I can use to assure I am meeting all of the requirements of my federal funding agency?



**Answer:** The NIH's Office of Laboratory Animal Welfare (OLAW) has created a brochure intended to communicate to investigators their responsibilities under PHS Grants Policy and PHS Policy on Humane Care and Use of Laboratory Animals. The brochure titled What Investigators Need to Know About the Use of Animals provides a succinct resource for investigators to quickly grasp the main expectations and requirements when using animals in research supported by the PHS. The brochure may be accessed as a PDF at <http://grants.nih.gov/grants/olaw/InvestigatorsNeed2Know.pdf> or in Word at <http://grants.nih.gov/grants/olaw/InvestigatorsNeed2Know.doc>.

**Question:** I have received an 'approval' from OESO for my protocol. Can't I begin using animals?

**Answer:** No. It is CRITICALLY IMPORTANT to recognize the while OESO, Employee Health, the IBC, and potentially other Offices on campus may be involved in review of certain animal use protocols, ONLY approval by the IACUC authorizes use of animals.

Each animal use application or amendment is routinely submitted to OESO, Employee Health, and DLAR for review of the relevant sections. In some cases, OESO training, a safety audit, or maybe immunizations (from Employee Health) may be required before the IACUC can approve the animal use application or amendment. The notice you receive from OESO (or others) indicates that there are no problems from their perspective, however it IS NOT an approval to begin animal use activities. The easiest way to think about this is that the IACUC approval can only occur AFTER the various agencies or Offices have 'cleared' the protocol and the people listed on the protocol.

While it is important to work with OESO or Employee Health or other Duke Offices to resolve any concerns with the protocol, the critical message is simple:

**A PROTOCOL (OR AMENDMENT) IS NOT APPROVED UNTIL THE PRINCIPAL INVESTIGATOR RECEIVES THE LETTER FROM THE IACUC THAT INDICATES THE PROTOCOL (OR AMENDMENT) IS APPROVED.**

