Types and Frequency of Inspections and Laboratory Visits Conducted by the IACUC

- Inspections Conducted Semi-Annually

DLAM Animal Housing Facilities
Institutional Animal Care and Use Committee (IACUC) members conduct the federally mandated inspections of all Division of Laboratory Animal Medicine (DLAM) maintained animal housing facilities (on and off campus) every 6 months. Representatives from DLAM and Environment, Health and Safety (EHS) participate in each inspection. The inspections are organized and led by the Office of Animal Care and Use (OACU) Training and Compliance Coordinators (TCC).

Principal Investigator (PI) Laboratories
OACU TCC perform the federally mandated inspections of a PI laboratory every six (6) months when a PI laboratory is approved for time limited housing of animals [i.e., Animal Procedural Space Exception (APSE)] or when research personnel perform any of the following procedures in the laboratory:
- Surgery (survival or non-survival)
- Aversive Behavioral Studies (or other studies involving pain and distress)
- Studies in Category E Studies
- Burn Studies

The purpose of the PI laboratory inspection is to ensure:
- the laboratory space meets Guide for the Care and Use of Laboratory Animals standards for the specific procedure;
- the IACUC has approved the procedures conducted in that location;
- the procedures are conducted as described in the application;
- the individuals conducting the procedure are listed on the approved application.

Note: if a core facility performs all of the animal procedures, a semi-annual inspection of the space is not required.
Inspections Conducted Quarterly

Satellite Facilities
The definition of a Satellite Animal Facility is an approved non-DLAM animal facility in which animals are housed for greater than 12 hours. The facility is maintained by the investigator. Federal regulations state that the authority and oversight of these facilities lies with IACUC.

The purpose of the federally mandated satellite facility inspection is to ensure:
- animals are observed by investigator staff daily;
- husbandry and cleaning duties are performed as specified in standard operating procedures;
- the facility is maintained according to standards in the Guide for the Care and Use of Laboratory Animals;
- the procedures conducted in the satellite are approved and conducted as described in the application;
- the individuals conducting the procedure are listed on the approved application.

In order to ensure compliance with federal and institutional Policies, the TCC conduct these inspections every 3 months.

Visits Conducted Every Two (2) Years

Informational Visits

By UNC institutional policy, OACU TCC conduct an informational visit every two (2) years for an investigator whose personnel perform the following procedures, whether in the laboratory or in an approved DLAM procedural space:

- Surgery (survival or non-survival) {only conducted within a DLAM space}
- Euthanasia
- Tissue harvest
- Injection(s)
- Non-aversive behavioral studies
- Other minor, non-surgical, non-painful procedures

(Note: if a core facility performs all of the animal procedures, then an informational visit is not required.)

The purpose of the informational visit is primarily to educate the PI and research personnel about IACUC policies and practice. Additionally, the inspection serves to ensure that the particular designated location is adequate, the procedures conducted in that location are approved and are conducted as described in the application, and the individuals conducting the procedure are listed on the approved application.
Visits Conducted Every Three (3) Years

“Procedural” Sessions:

Federal regulations and the Guide for the Care and Use of Laboratory Animals (Guide) require institutions to ensure compliance according to IACUC approved protocols through Post-Approval Monitoring (PAM). A variety of mechanisms can be used to facilitate ongoing protocol assessment and regulatory compliance. At UNC this federal mandate is fulfilled through a “Procedural” which is conducted by OACU TCC.

OACU TCC will observe one surgeon per lab (the most representative person or the LAC). The laboratory receives an observation session every three (3) years or when the person whom we observed, leaves the lab, whichever comes first. Individuals conducting the following procedures will be assessed:

- Surgical Procedures (survival or non-survival)
- Aversive Behavioral Studies (or other studies involving pain and distress)
- Studies involving Pain Category E
- Burn Studies

New features of the “Procedural” (may combined with the semiannual inspection when possible):

An OACU TCC will meet with one of the experienced laboratory personnel who is currently performing any of the procedures indicated above. OACU TCC will review the approved procedure as outlined in the applicable Animal Care Application (ACAP) by evaluating the degree of proficiency and compliance.

- The “Procedural” will consist of conversation between a surgeon/researcher within the lab (i.e., LACs, senior surgeons, or others actively performing the procedure or training lab members) and an OACU member regarding the procedure.
- The use of a live animal is **NOT** required. Instead, the surgeon/researcher will set up for and present the procedure from the instrument and animal preparation stage to recovery/euthanasia as it would be performed on a live animal. The use of photos, slides, tools, demonstrations, etc. are all acceptable methods for illustrating techniques used during a procedure.
- The OACU member will follow the demonstration with a briefing to include:
  - Potential problems identified during the procedure along with suggestions for possible protocol amendment
  - Possible deficiencies noted with suggestions about how to resolve them before the follow-up inspection
  - Information regarding current issues in lab animal medicine (e.g. new analgesics or anesthetics) or updates in IACUC & DLAM policies and procedures

Updated 6/2012
• A report including details of the “Procedural” and suggestions for improvement will be sent to the LAC, PI, and surgeon.
• Upon successful completion of this first “Procedural”, future combined sessions will occur once per 3 year period (unless there has been a significant turnover of laboratory personnel or if an additional observation is requested).

All applicable items stated below will be discussed and evaluated during the procedural session.

1) Surgical area:
   a) Cleanliness
   b) Ability to sanitize surfaces
   c) Separate areas for surgical preparation, recovery, and surgical procedure
   d) Proper preparation of caging for animal while under an anesthetic

2) Adherence to approved procedures:
   a) Name and purpose of drugs administered
   b) Dosage and/or volume of drugs administered
   c) Route of administration
   d) Frequency of drug administration
   e) Surgeon understands and confirms appropriate plane of anesthesia

3) Surgical preparation of animal:
   a) Proper eye lubrication
   b) Adequate removal of hair with appropriate technique
   c) Application of skin disinfectants with proper technique and supplies

4) Surgeon and sterile field preparation:
   a) Donning of required personal protective equipment
   b) Adherence to IACUC Guidelines regarding sterilization of instruments and packs
   c) Comprehension of what objects or materials comprise a sterile field
   d) Proper use and application of sterile gloves (if required)
   e) Proper techniques for manipulation of non-sterile objects
   f) Application and use of sterile drape

5) Evaluation of surgical techniques:
   a) Proper quantities, selection and use of instrumentation
   b) Proper use of materials (eg. appropriate suture)
   c) Proficiency and skill

*Some microsurgery procedures do not require the donning of sterile gloves or application of sterile drapes. Please contact the OACU to inquire about the specifics of your surgical preparation.