Animal Care Application Review and Maintenance
UNC Institutional Animal Care and Use Committee (IACUC)

- Responsible for oversight and ongoing assessment of the animal care and use program and its components
- Minimum of 5 members, consisting of at least
  - One veterinarian
  - One practicing scientist
  - One non-scientist member
  - One member not affiliated with the institution

- UNC Chapel Hill IACUC has 12 primary members plus alternates
- Meet once per month to review various aspects of the program as well as the animal care applications
- Supported by the Office of Animal Care and Use
Two Types of Animal Care Applications

New Application

- Completely new study, not previously seen by the IACUC

Continuation Application

- Ongoing study, previously reviewed by the IACUC
- May be expiring, having reached the end of the 3 year approval
- May have been a pilot study, now complete
- PI could have fewer animals than expected at this point in study
The application is a binding contract describing every aspect of the in-life portion of an animal use study.
ACAP Menus

IACUC
- Start A New Animal Application
- IACUC Meeting Dates & Submission Deadlines
- PI Certification Inbox (0)
- Register for a Class/Lecture
- View Your Registrations (research profile, animal handler form, DLAM & IACUC orientations, training records)
- Request a Grant Congruency Review for your JIT or Notice of Award
- Reporting Animal Mistreatment or Animal Protocol Noncompliance
- Policies and Procedures
- IACUC Home Page

DLAM
- DLAM Home Page (facilities, per diem charges, forms, resources, newsletter)
- Billing Manager Assignment (1)
- Chart Field Assignment (1)
- View Invoices
- Veterinary & Technical Services
- DLAM FAQ

EHS
- Environment Health & Safety Home Page
- Lab Safety Plan

Contact

ENVIRONMENT, HEALTH & SAFETY
University of North Carolina - Chapel Hill
1120 Estes Drive Extension
Chapel Hill, NC 27599
919.962.5507

Close
Accessing Approved Applications in ACAP

<table>
<thead>
<tr>
<th>IACUC ID</th>
<th>Expiration Date</th>
<th>Title</th>
<th>Status</th>
<th>Link</th>
</tr>
</thead>
<tbody>
<tr>
<td>16-_____</td>
<td>2/28/2017</td>
<td>Principles of Aseptic Technique</td>
<td>Approved</td>
<td>Create a new/continuation application from this submission</td>
</tr>
<tr>
<td>15-_____</td>
<td>1/31/2017</td>
<td>IACUC Holding Application</td>
<td>Approved</td>
<td>Create a new/continuation application from this submission</td>
</tr>
<tr>
<td>14-_____</td>
<td>5/31/2017</td>
<td>Techniques in the Laboratory Rat</td>
<td>Approved</td>
<td></td>
</tr>
<tr>
<td>13-_____</td>
<td>10/31/2016</td>
<td>Techniques in the Laboratory Mouse</td>
<td>Approved</td>
<td></td>
</tr>
<tr>
<td>13-_____</td>
<td>2/29/2016</td>
<td>Principles of Aseptic Technique</td>
<td>Continued</td>
<td></td>
</tr>
<tr>
<td>12-_____</td>
<td>1/31/2015</td>
<td>IACUC Holding Application</td>
<td>Continued</td>
<td></td>
</tr>
</tbody>
</table>
## Item List Page

- **General Information**
- **Addendum Checklist**
- **Attachments**
- **Personnel**
- **Additional Funding Sources/Title Changes**
- **Scientific Justification for Animal Species**
- **Housing, Locations and Confinement**
  - **Conducting Procedures and/or Housing Animals - DLAM Facility versus Investigator-maintained space**
  - **Satellite Animal Facility Form**
- **Reduction, Refined, Replacement, and Animal Numbers**
  - **Alternatives to Animals Classified in USDA Pain Categories D or E**
- **Details of Animal Use**
  - **Tumor Studies in Animals**
  - **Collection of tissue from live or dead vertebrate animals**
  - **Collection of blood or body fluids from live or dead vertebrate animals**
- **Animal Care**
  - **Anticipated Animal Pain & Distress**
- **Items not covered in other parts of the application**

***Buttons:***
- Submit Application
- Delete Application
- **Preview Application**
- **Save & Exit**
Addendum Checklist

1.1 Are there confidential or potentially patentable issues?

1.2 Will collaborator(s) or Core Facilities, other than the PI, Co-PI or approved personnel within the PI’s laboratory, perform any procedures on animals in this animal use application?

3.1 Will animals be housed or used in any DLAM, investigator laboratory, or other space?

3.2 Will live animals be removed from a DLAM Housing Facility or an IACUC-approved Investigator-maintained Housing Space and taken to another location for temporary holding and/or manipulation?

3.3 Will animals be housed long-term in an Investigator space? (Satellite Facility: an Investigator-maintained, non- DLAM facility where animals are housed on a long-term basis and are cared for by the principal investigator’s laboratory personnel.)

3.4 Are study animals now or have they ever been free-ranging wildlife?
Keep in Mind...

- When using the services of a Core Facility or Collaborator an Animal Services form is required
- Schedule G forms are only reviewed by the IBC once per month
- Most exception requests must be reviewed by the full IACUC
- Checking all online and hands on training before submission can prevent delays
Things to Avoid

- Writing an application for more than one species
- Uploading tables directly into the text of the application
- Opening ACAP in more than one browser window
Don’t Forget!

- All techniques described in application must be listed in the Personnel section
- Check all online and hands on training at submission
- Preview application PDF before submission!
Application Pre-Review

EHS
- Agents, Cell Lines, Transgenics
- Hazard Forms
- IBC Forms
- Lab Worker Form

T&C
- Personnel Roles
- Hands-On Training
- Surgical Sections
- Locations
- Procedures

OACU
- Online Training
- Core and Collaborators
- Attached Forms
- Updated Information
- Personnel Follow-Up

DLAM Veterinarians conduct their reviews during this time as well!
IACUC Member Review

- Every application is assigned a primary and veterinary reviewer
- Primaries receive applications 1-2 weeks in advance
- Veterinary reviewers receive applications during pre-review
- At the monthly IACUC meeting Primary and Veterinary reviewers discuss their concerns with the rest of the committee

- Approved
- Approved after modifications
- Withheld
Post-Meeting Process

IACUC Meeting

Application Reopened

New Comments Added

PI Revises & Resubmits

Revisions Reviewed

All Comments Addressed?

Application Approval

YES

NO
Application Approval

- A notification email sent to PI, Co-PI, LAC, and Official Contacts
- Special circumstances
  - Exception request approval
  - Protocol monitoring reasons and deadlines
  - Messages from the reviewers
- Continuation applications require extra steps by the OACU
  - Must link the old protocol to the new, approved application in ACAP
  - If old protocol has animals in house a separate email is sent about animal transfer and cage cards
- The application is good for 3 years, but annual renewals are required
- The PI is sent renewal reminders at 12 weeks and again at 8 weeks before the expiration date every year
Post-Approval Actions

Annual Renewals

- Required for all protocols
- PI must answer a series of questions
  - Is study is active?
  - Have there been any adverse events or unexpected deaths?
  - Do the objectives and timeline remain consistent with protocol?
  - Any changes expected in upcoming year?
- Additional questions for protocols involving USDA covered species

Amendments

- Required for all significant changes to protocols
- Handling of review depends on changes requested
  - Protocol changes by email
  - Administratively handled changes
  - Designated Member Review (DMR)
  - Full Committee Review (FCR)
- Any IACUC member can request full committee review for any amendment
### Various Types of Amendments

<table>
<thead>
<tr>
<th>Changes by Email</th>
<th>Termination of Protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Removal of Personnel</td>
</tr>
<tr>
<td></td>
<td>Change in Animal Housing Location Between Buildings</td>
</tr>
</tbody>
</table>
# Various Types of Amendments

<table>
<thead>
<tr>
<th>Designated Member Review</th>
<th>Addition of new procedures</th>
<th>Addition of rodent strains with significant health phenotypes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in study objectives</td>
<td>Change in degree of invasiveness or of procedure pain and distress</td>
<td></td>
</tr>
<tr>
<td>Unanticipated or marked increase in clinical signs or animal deaths</td>
<td>PI Transfers</td>
<td></td>
</tr>
</tbody>
</table>
Various Types of Amendments

May Require Full Committee Review

Amendments that include a request for exception to IACUC policy

Addition of surgery to a non-surgical application
New Protocol Submission Required

- **Species**
  - Change in animal species

- **Purpose**
  - Change in overall purpose of the study

- **Numbers**
  - More than 25% increase to original animal numbers
Application Termination

- Send an email to the IACUC mailbox
  - Application is checked to verify all animals have been used or transferred
  - Terminate when animals are gone
- If a PI is leaving, they should contact the OACU to make arrangements to terminate their protocols
Contacting the Office of Animal Care & Use

- New & Continuation Applications
- Annual Renewals
- Amendments
- Title/Funding Changes
- Grant Congruency Reviews
- Scheduling Hands-On Classes and Lectures
- Inspections
- Animal Concerns

- Phone: 919-966-5569
- Email: IACUC@med.unc.edu
- IACUC Website: http://research.unc.edu/offices/iacuc/