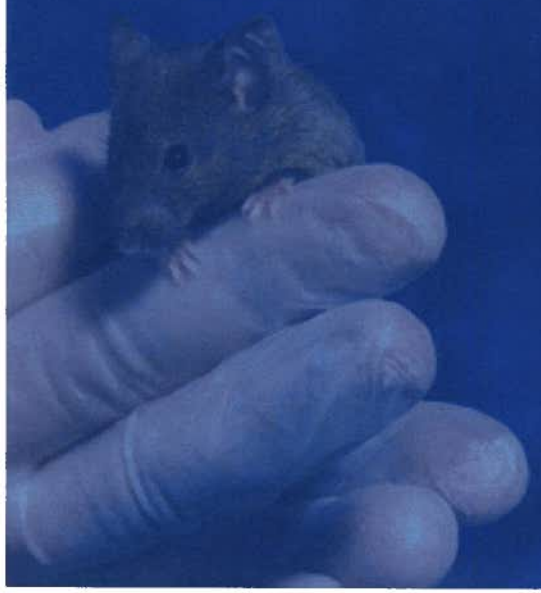
Preparation of the NCI Animal Study Proposal



Presented by:
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and
Angela Stahl, NCI-Frederick ACUC Coordinator

Key Topics of Discussion

Animal Care and Use Program

- Overview of the Animal Care and Use Committee (ACUC) and its responsibilities
- Federal Regulations and Policies
- Investigator and Animal User responsibilities
- Completing the Animal Study Proposal (ASP) Form
- ASP review process

Why does the ACUC exist?

- Animal Welfare Act
- PHS Policy on the Humane Care and Use of Laboratory Animals
- Guide for the Care and Use of Laboratory Animals
- Association for Assessment and Accreditation of Laboratory Animal Care International

Who serves on the ACUC?

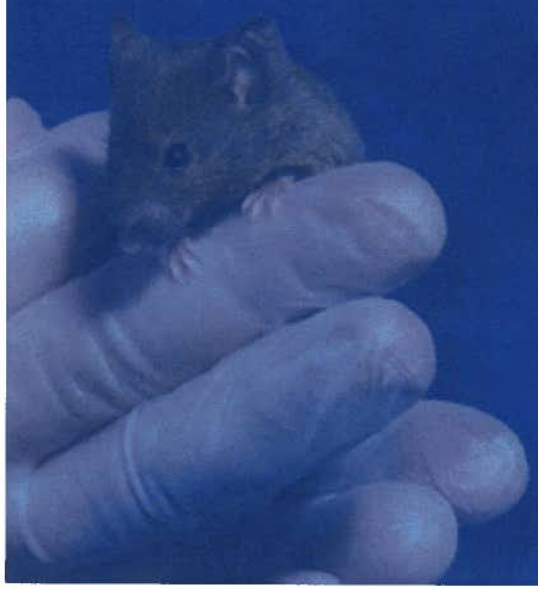
Chair
Attending Veterinarian
Scientists
Unaffiliated and Nonscientific Member
Safety Representative

What does the ACUC do?

- Assist with proposal submissions
- Review proposals for adherence to Federal and institutional guidelines and policies
- Develop guidelines
- Review program and recommend improvements
- Inspect animal facilities
- Investigate animal care and use concerns

Principal Investigator (PI) and Animal User

What are your responsibilities?



PI and Animal User's Responsibilities

- Comply with Federal Regulations and ACUC Guidelines
- Ensure that all individuals listed on a proposal are properly trained and enrolled in the occupational health program
- Ensure adherence to content of approved proposal
- Notify ACUC of changes to proposal in advance…*failure to do so may result in suspension of animal activities*
- Complete annual and triennial review of proposal
- Update training every three years

Things to Remember …

- Conscientious research
- Maintain public trust
- Animals are living creatures that experience pain and distress
- It is your responsibility as a researcher to ensure that your animals are properly and responsibly cared for
- Be familiar with the behavioral characteristics of your animal subject as a mechanism for identifying potential pain, distress, or health related issues

Animal Study Proposals

A step-by-step process …

- Consult with your attending veterinarian and ACUC coordinator
- Consult with your facility manager
- Consult with the safety representative
- Refer to the ACUC and ARAC guidelines (Bethesda)

Refer to the ACUC Policies and Guidance

- Animal Numbers Justification
- Humane Endpoints
- Transportation
- Experimental Neoplasia
- MAP/MTBM Testing
- Breeding and Weaning
- Genotyping
- Needle size/dose volume
- Alternatives to Ascites
- Perioperative Analgesia
- Postoperative Pain Evaluation
- Euthanasia
- Renewal and Annual Review

Animal Study Proposal Content

- Follow the ASP form directions
- Ensure ALL staff is included (and adequately trained) for all procedures in the ASP
- Rationale and justifications
- Detail ALL procedures that animals will undergo
- Reference applicable policies and guidelines
- Have questions … Please ask

Animal Study Proposal Rationale

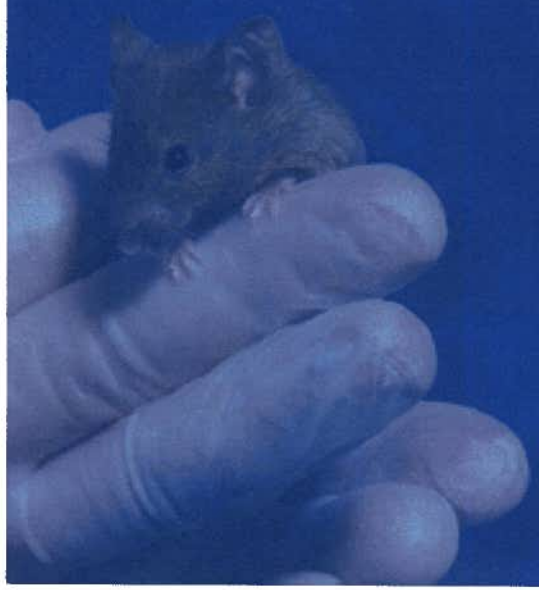
- For study objectives, use non-technical language
- Animal number justification, provide a scientific rationale for group size and total number of animals required
- For procedures outside of the ACUC guidelines, scientific justification is required

Alleviate Pain and Distress

- Consideration of alternatives
- Recognition
- Known or potential adverse effects
- Anesthetics and Analgesics
- Veterinary consultation

Humane Endpoints

- Expectations
- Physical appearance
- Physiological changes
- Behavioral or activity changes
- Changes in body weight



Frequent observation and veterinary staff involvement are key factors for ensuring appropriate humane endpoints

Major Survival Surgery

Any surgery that penetrates and exposes a body cavity or that produces substantial physical or physiological impairment is considered to be major survival surgery (e.g., laparatomy, thoracotomy, craniotomy, joint replacement, and limb amputation)

Please consult with the veterinarian in advance of proposal submission

Post-Operative Care

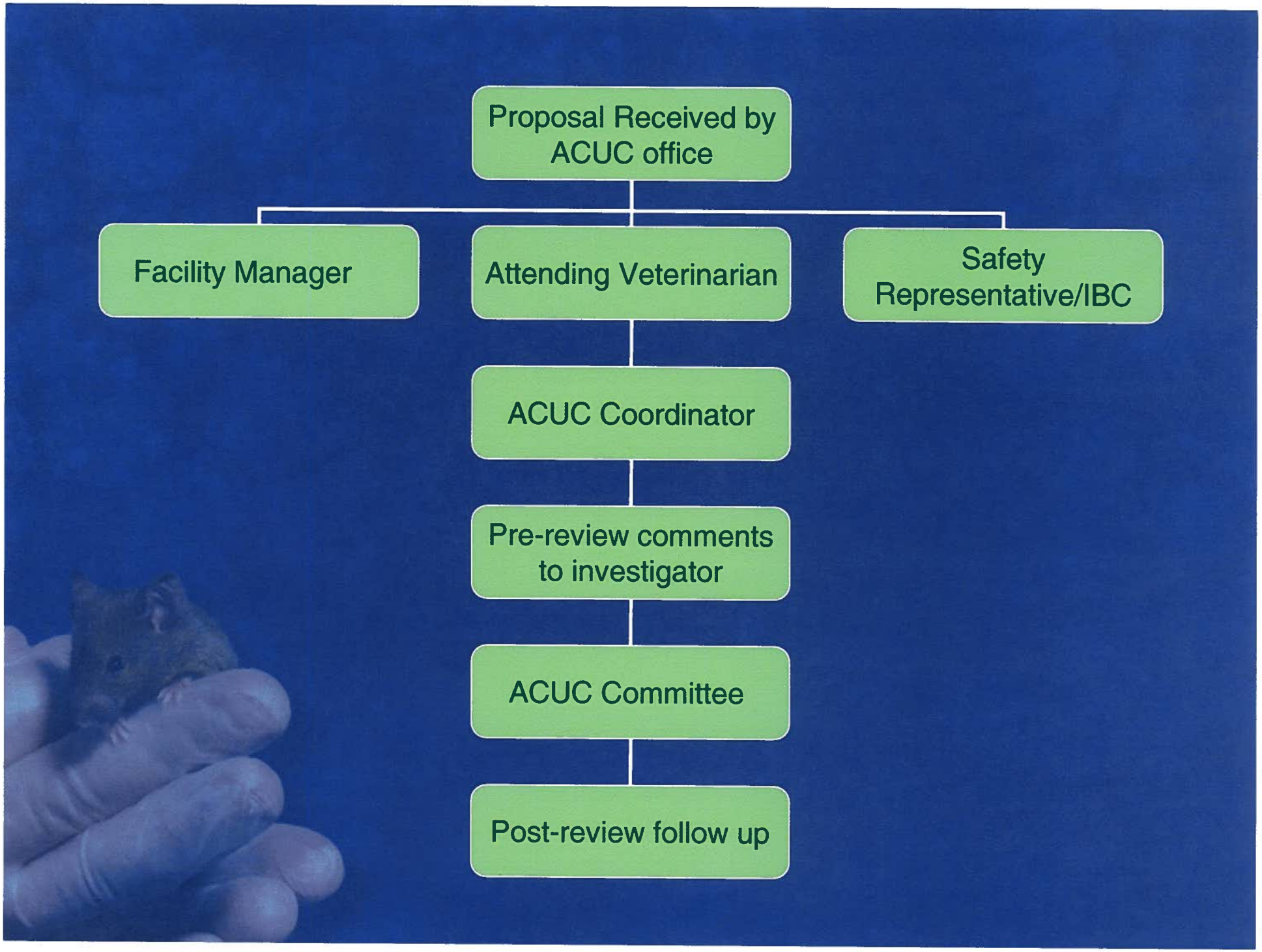
- Individual responsible for care
- Monitoring
- Analgesics Used (agent, volume, route, dose, needle size)
- Wound closure removal
- Special housing
- Body temperature

How do I assign pain or distress categories?

Category 1	Category 2	Category 3
Minimal, transient, or no pain or distress *Any procedures not involving anesthesia (e.g., breeding, injections)*	Pain or distress is relieved by appropriate measures *Any animal receiving anesthesia/analgesia to relieve pain must fall into this category*	Pain or distress is not relieved *Consult a veterinarian if you are proposing to conduct procedures that fall into this category*

Animal Study Proposals

Review Process


Proposal Received by ACUC office
Facility Manager
Attending Veterinarian
Safety Representative/IBC
ACUC Coordinator
Pre-review comments to investigator
ACUC Committee
Post-review follow up

Modification or New Submission

How do I know what to submit for a change?

Modification	New Proposal
All changes that fall under the same scope of study as the original proposal Surgery, procedures, bleeding, personnel, holding location, increase of animal numbers, species, strain, hazardous agents, etc.	If the changes you are proposing do not fall under the same scope of study as the original proposal
Modification form (Bethesda) Memorandum (Frederick)	New ASP Form

Proposal Reviews

What is my responsibility?

Review **every year**

Renew **every 3 years**

Animal Welfare Concerns

- Veterinary Staff
- ACUC Chairperson
- Institutional Official
- Office of Laboratory Animal Welfare

Contact Information

NCI-BETHESDA

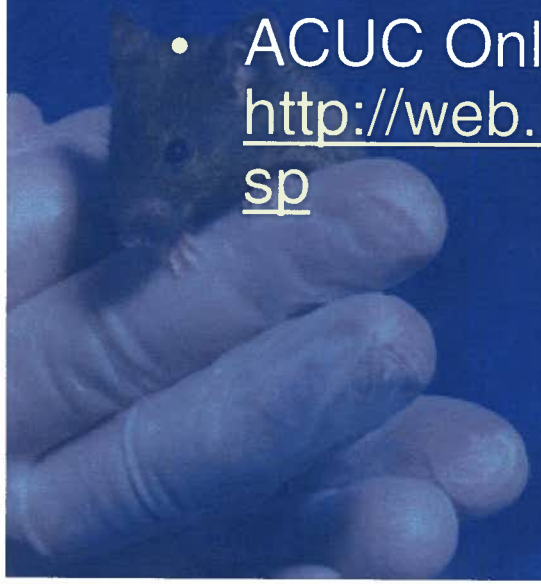
Chand Khanna, ACUC Chair.....301-594-3406
Christine (Tina) Sadr, ACUC Coordinator.....301-435-5733
Attending Veterinarians.....301-496-1866
- John Dennis, DVM
- Rhonda Pung, DVM
- Ashley Reynolds, DVM
- Jeremy Smedley, DVM

NCI-FREDERICK

Melinda Hollingshead, ACUC Chair.....301-846-5680
Angela Stahl, ACUC Coordinator.....301-846-7544
Raja Sriperumbudur, DVM (Facility Veterinarian).....301-846-5577
Jeremy Smedley, DVM (Attending Veterinarian).....301-846-5195

Helpful Links - Bethesda

- NCI-Bethesda ACUC website: http://web.ncifcrf.gov/rtp/lasp/intra/acuc/beth/default.asp
- ACUC Guidelines: http://web.ncifcrf.gov/rtp/lasp/intra/acuc/beth/RegulationsPolicies.asp
- Animal Study Proposal & standard language: http://web.ncifcrf.gov/rtp/lasp/intra/acuc/beth/AnimalStudyProposal.asp
- OACU PI & animal user training (register & online course): http://oacu.od.nih.gov/training/index.htm

Helpful Links - Frederick

- NCI-Frederick ACUC website: http://web.ncifcrf.gov/rtp/lasp/intra/acuc/fred/main.asp
- ACUC Guidelines: http://web.ncifcrf.gov/rtp/lasp/intra/acuc/fred/guidelines_nci.asp
- Animal Study Proposal form and helpful hints: http://web.ncifcrf.gov/rtp/lasp/intra/acuc/fred/proposal.asp
- ACUC Online Training: http://web.ncifcrf.gov/rtp/lasp/intra/acuc/fred/training.asp