NIEHS Animal Care and Use Committee Guideline

APPOINTMENT OF COMMITTEE MEMBERS

The Institutional Official is the NIH Deputy Director for Intramural Research, Dr. Michael Gottesman. Authority for the Animal Care and Use Program is delegated to the NIEHS DIR Scientific Director, Dr. Darryl Zeldin, who appoints the NIEHS Animal Care and Use Committee (ACUC). Appointments are generally for a three-year term and reappointments are possible.

COMMITTEE COMPOSITION

The committee must be composed of at least five members and usually consists of 11-15 members. The Scientific Director appoints all members of the ACUC including the Chairperson and Deputy Chairperson. Scientific members represent the programs using animals at NIEHS. Every effort is made to fairly represent the major Laboratories/Branches using animals. No more than 3 members are appointed from any one branch. A member of the Health and Safety Branch is appointed to serve as a safety and health resource to the committee. A non- scientist and a non-affiliated member are required. The Chief of the Comparative Medicine Branch (CMB) serves as the NIEHS Animal Program Director and Attending Veterinarian and is a permanent member of the committee. The NIH Ombudsman serves as ex-officio non-voting members of the committee.

TRAINING OF ACUC MEMBERS:

New ACUC Members are given an orientation to NIEHS ACUC procedures, policies, and member responsibilities by the ACUC Program Coordinator. A PowerPoint presentation has been developed for this purpose and meets all NIH requirements for ACUC member training. New members are also provided with links and online access to NIEHS ACUC reference documents (listed below). Whenever possible, new members are not designated as primary reviewers until after attending several ACUC meetings to become familiar with the ACUC review process. Once assigned as a primary reviewer, the new member works closely with a member of the CMB staff who assists them with the initial review procedures.

Committee members are encouraged and supported financially by the Office of the Scientific Director to attend ACUC-related training opportunities such as Public Responsibility in Medicine and Research (PRIM&R), The North Carolina Association for Biomedical Research (NCABR), and the Office of Laboratory Animal Welfare (OLAW) sponsored courses such as “IACUC 101” or “ACUC Advanced”. Webinars, such as those presented by OLAW, are available at NIEHS and are frequently attended by ACUC members. ACUC members are regularly apprised of other issues regarding animal welfare through forwarded postings, published articles, and online newsletters such as Animal Research News & Analysis, NCABR Media Scan, and AMP News Service.

ACUC MEETINGS

The committee meets monthly, generally on the fourth Thursday of the month. A quorum, defined as greater than 50% of the voting members of the ACUC, is required for the committee to conduct business. No member may participate in the approval of a research project in which the member has a conflicting interest or contribute to a quorum for the approval of the research project. With the exception of the Heads of an NEHS Core, any committee member who is the Principal Investigator (PI) or listed participant on an Animal Study Proposal (ASP), must leave the room during discussion and deliberation of that ASP. Approval of an ASP/amendment requires an affirmative vote by a majority of the quorum present. Any action by the committee that is not unanimous is documented in the meeting minutes. Minority viewpoints are also documented in the ACUC meeting minutes and in the semiannual report.

RECORD KEEPING

Approved ASPs/amendments are electronically signed within the eSirius facility management application. The electronic signature of the PI's Lab/Branch Chief indicates review and concurrence on the basis of scientific merit. The Scientific Director's signature is required for proposals submitted by a Laboratory/Branch Chief. Final approval of the ASP/amendment, considered the official record of the Chair signature/dating, is recorded using the "Approve Now" function in eSirius. ACUC meeting minutes and semiannual reports, approved by the committee, are sent to the NIEHS Scientific Director and the NIH Office of Animal Care and Use (OACU). All ACUC records are maintained for a minimum of three years. ASP files are maintained for a minimum of 3 years following completion of the study in accordance with NIH Manual Chapter 1743: "Keeping and Destroying Records."

RESPONSIBILITIES OF THE COMMITTEE

- Advise the Scientific Director on all aspects of the animal care and use program, facilities, or personnel training.
- Advise investigators regarding animal care and use.
- Hold monthly meetings, maintain files of minutes, memoranda, and project review documents. Notify investigators in writing of results of animal study proposal reviews.
- Review and approve, require modifications to secure approval, or withhold approval of all proposals related to the use of animals in research studies.
- Review and approve, require modifications to secure approval, or withhold approval of proposed changes regarding the care and use of animals in ongoing activities.
- Review animal care and use program and inspect the animal facilities, including

satellite facilities, animal study areas, and animal transportation vehicles at least semiannually using The Guide for the Care and Use of Laboratory Animals as a basis for evaluation. Submit written reports, signed by a majority of ACUC members to the NIEHS Scientific Director and the NIH OACU (submit in April and October).

- Review all ongoing animal use activities annually.

- Prepare USDA "Annual Report of Research Facility." The NIEHS is a federal facility and as such, it is not required to be registered with the USDA nor is it subject to USDA inspection. However, it is bound by the USDA regulations and submits an annual report to the NIH OACU for inclusion in a composite NIH Annual Report to USDA.

- Review and, if warranted, investigate concerns involving the care and use of animals resulting from public concerns or from reports of non-compliance received from laboratory or research facility personnel. Report all instances of non-compliance to the Deputy Director of Intramural Research/OACU to effect appropriate Institutional communications with OLAW. Notify the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC), as required.

- Complete the Humane Care and Use of Animals in Research at NIEHS training course.

- Provide orientation and training to new ACUC members.

- Exert authority to suspend activities involving animals, when warranted.

- Attend monthly NIH Animal Research Advisory Committee (ARAC) meetings. The Chair, Deputy Chair, ACUC Program Coordinator, and/or Animal Program Director attend these meetings via videoconference and report back to the ACUC each month.

REVIEW METHODS FOR SIGNIFICANT CHANGES

An ACUC-approved ASP is required for work involving both vertebrate and invertebrate animals at NIEHS. An ACUC-approved amendment is required for significant changes regarding the use of animals in on-going activities described in an ASP.

There are two valid methods of ACUC review allowed by the PHS Policy (1) full-committee review by a convened quorum of the members of the ACUC, or (2) designated member review by one or more members. [3]

1. **Full Committee Review (FCR)**: *1

This method is used for ASP's and amendments that describe the following significant changes

- Novel concepts/Change in Study Objectives
- Changes that may involve an increase in potential pain/distress to animals
- Column E studies
- Survival surgery for which the PI/lab has no documented experience at NIEHS.
- Prolonged restraint (>20 minutes)*4
- Exceptions to The Guide
- Hazardous Agent or drug usage for which the PI has no documented experience at NIEHS
- Procedures that raise concerns during pre-review.

Process: CMB veterinarians, the ACUC coordinators, and the committee member assigned as the primary reviewer conduct a preliminary review of each proposal and amendment and add comments/questions/requests for clarification in the electronic submission. The submission is returned to the investigator requesting revision and, if needed, a meeting with the PI is requested to discuss the submission with the veterinarian, primary reviewer, and/or the ACUC office. Revisions must be received 6 business days before the meeting. Revisions of each proposal/amendment are distributed to ACUC members for their review at least 3 business days prior to the convened meeting. Each primary reviewer documents review of the proposal in the online submission, which facilitates their presentation of the submission at the convened committee meeting. After discussion led by the primary reviewer each proposal is brought to a vote. The proposal may be approved, require modifications to secure approval, or approval withheld.

The Chair approves the ASP/amendment with the meeting date by electronic signature, which denotes finalization of the approval process. The PI is contacted in writing with the committee's decision. The correspondence details the procedures that must be adhered to when the study is initiated (submission of the animal disposition sheet, experimental summary sheet, notification of study initiation with VMS/ARS, etc). Animal ordering and initiation of animal activities described in the ASP/amendment can then proceed.

If the submission requires modifications to secure approval, no work may be initiated on the proposal. As originally approved by the full committee at the December 2013 ACUC meeting and reaffirmed annually by the ACUC, in writing, the quorum of members present at a convened meeting may decide by unanimous vote to use Designated Member Review (DMR) subsequent to FCR when modification is needed to secure approval. However, any member of the ACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol. If DMR is approved and FCR is not called, the date that the designated reviewer approves the ASP/amendment (documented on the approval correspondence and in the electronic protocol management system) is considered to be the approval date.

If approval is withheld no work may be initiated on the proposal and it must come back

to the full committee for final review and approval. The ACUC meeting date at which a proposal is approved is considered the date of approval.

2. Designated Member Review (DMR)

Designated Member Review is used for ASPs and amendments that are outside of the scope of those requiring FCR as described above.

Process: The designated member reviewer is selected based upon expertise in the subject matter, whenever possible, and assigned by the ACUC Chair. CMB veterinarians, the ACUC coordinator, and the committee member assigned as the designated member reviewer conduct a preliminary review of each proposal and amendment and add comments/questions/requests for clarification in the electronic submission. ACUC members are provided with the ASP number, title, PI name, and a brief description of the proposal via electronic correspondence and are asked to respond within 24 hours if they wish for the submission to be reviewed by FCR. The full ASP/amendment is available to all committee members, upon request. If full committee review is not requested the designated member has the authority to approve, require modifications to secure approval, or refer the submission to full committee for review. Actions taken on any designated member review are reflected in the ACUC meeting agenda and minutes. The date that the designated reviewer approves the ASP/amendment (documented on the correspondence and in the electronic protocol management system) is considered to be the approval date.

Examples that can be reviewed by Designated Member Review:

Animal Study Proposals:

- ASP's that involve only invertebrates
- Breeding and production only
- Tissue collection
- Change in PI
- ASP renewals where no changes have been made from the previous submission and no adverse events have occurred.

Amendments:

- Change in animal use location outside the animal facility to a new lab location that has not previously been overseen by the ACUC. The change is captured in the semiannual laboratory site visit documentation and reflected in the ASP by the ACUC Office.

- Transfer of animals to an offsite collaborator who is AAALAC Accredited and OLAW Assured while maintaining ownership of the animals post-transfer. (requires a copy of the approved protocol from the receiving institution)

- Change involving only invertebrates.

- Increase in animal numbers of >10% (based on the number approved in the original ASP)

- Change in species

- Change in animal species/stock/strain with no expected adverse phenotypes.

- Husbandry issues
    - changes in feed or water that is part of scientific portion of study
    - changes in type of caging or bedding that is part of scientific portion of study

  Note: The use of metabolism cages for longer than 24 hours, which represents an exception to The Guide, is considered to be a significant change requiring full committee review.

- Addition of non-invasive procedures such as breeding/backcrossing/behavioral phenotyping/imaging

- Change in number or frequency of sampling timepoints (unless it potentially impacts health or well-being of the animal)

- Change in route, concentration, or volume of compound administration (unless it potentially impacts the health or well-being of the animal)

- Change in dosage or dosing frequency (unless it potentially impacts health or well-being of the animals)

- Changes that may involve a decrease in potential pain/distress to animals

- Feed restriction $\leq$ 24 hours in duration (unless it potentially impacts the health or wellbeing of the animal)

- Addition of survival surgery for which the PI/lab has documented experience and previous NIEHS ACUC approval.

- Hazardous Agent or drug usage for which the PI has documented experience at NIEHS.

- Changes that could impact personnel safety.

In any of these examples, if the veterinary preliminary review indicates any significant issues, potential impact on animal health or well-being, or if there is any question about the significance of the change, it will be referred to full committee for review.

3. Veterinary Verification and Consultation

Veterinary Verification and Consultation (VVC) is used for the review and approval of modifications to ASPs/amendments by a veterinarian authorized by the ACUC an applies only to the changes below. The veterinarian is not conducting a DMR on behalf of the ACUC, but is serving as a subject-matter expert to verify that compliance with the ACUC policies are appropriate for the animals in the following circumstances.

a. Addition of single housing
b. Changes in anesthesia and/or analgesia.
c. Change in method of euthanasia (as long as the new method is approved in the AVMA Guidelines for the Euthanasia of Animals.
d. Change in NIEHS approved blood collection site or volume (unless it potentially impacts the health or well-being of the animal)
e. Change in vehicle of compound administration (unless it potentially impacts the health or well-being of the animal)

Process: CMB veterinarians and the ACUC office staff conduct a preliminary review of each proposal or amendment. A pre-review with questions and requests for clarification is sent to the investigator and the veterinarian. The veterinarian can refer any request for modification to the ACUC for FCR or DMR for any reason.

Actions taken on any VVC are reflected in the ACUC meeting agenda and minutes. The date that the veterinarian approves the specific change is documented in the monthly ACUC meeting agenda and minutes.

ADMINISTRATIVE METHODS OF REVIEW

An administrative process is in place to review the following minor changes:

- Addition of trained personnel (change in PI requires new ASP and designated member review) *2 This is documented in the meeting agenda and minutes.
- Increase in animal numbers of ≤ 10% (based on number approved in original ASP)*1 This is documented in the meeting agenda and minutes.
- Correction of typographical errors, grammar and contact updates.

Process: The ACUC office staff conducts a preliminary review of each amendment. A pre-review with questions and requests for clarification is sent to the investigator, if required and ensures appropriate documentation/training/nomenclature is included prior to approval.

Administrative actions, with the exception of the correction of typographical errors, are reflected in the ACUC meeting agenda and minutes.

PROTOCOL PROCESSING PROCEDURES

1. **Standard Review (FCR/DMR):**
   Animal Study Proposals and amendments are submitted to the ACUC Office and undergo a pre-review by the ACUC staff and CMB veterinarians. Materials

submitted by the first of the month, will be reviewed at that month's ACUC meeting. Materials for review at an ACUC meeting are distributed to committee members at least 3 business days prior to the meeting. Investigators are notified in writing of the outcome of review of their proposals.

2. **Expedited Review**:
   On rare occasions, i.e., when limited availability of animals or facilities requires a rapid response, an expedited review of an animal study proposal or amendment may be requested.

Process: The proposal/amendment is submitted with an expedite request, completed by the PI and is reviewed by the ACUC coordinator, a CMB veterinarian, and the ACUC Chair with emphasis placed on the scientific need for the requested expedited review. The Chair determines whether an expedited review is warranted. The full ASP/amendment is then distributed to all ACUC members with a request for expedited review including the justification for the request. Committee members are given 24 hours to review and call for full committee review, if desired. Response from a committee quorum is assured and documented. If any committee member requests full committee review, the expedited process is stopped and the proposal/amendment is sent to the full committee for review at a convened meeting. If full committee review is not requested, the ACUC Chair designates a member to review the proposed research project with authority to approve, require modifications to secure approval, or refer to the ACUC for full committee review. Actions taken on any expedited review are reflected in the ACUC meeting minutes. The date that the designated reviewer approves the ASP/amendment (documented on the correspondence and in the electronic protocol management system) is considered to be the approval date.

Annual review:
All ongoing proposals are reviewed annually. The PI reviews the proposal and completes a "Continuing Review" in the online protocol management system indicating whether the study is to be continued without changes or withdrawn and provides a brief progress report and personnel update. The review is assigned to DMR and annual reviews are listed on the ACUC agenda and minutes. Members can call for full committee review of any annual review.

Semiannual Program and Facility Review:
Review of the NIEHS animal care and use program is an ongoing process. Issues are raised at each ACUC meeting, e.g., revision of the ASP form and instructions, revision of program review procedures, Standard Operating Procedures (SOPs), and discussion of issues raised at the monthly NIH ARAC meetings. In addition, as part of the semiannual review process, the committee members formally analyze and discuss the animal care and use program at a convened ACUC meeting, using the NIEHS program description prepared for AAALAC and OLAW checklist as a guide. ACUC members are assigned to each of five major topics for review: Institutional Policies, Veterinary Care, Laboratory Animal Husbandry and Physical Plant, Special Considerations, and

Laboratory Visitation during the spring semi-annual review. Members are assigned three major areas of review: Institutional Policies and Responsibilities, Veterinary Care, and Lab Site Visits during the fall review. Subcommittees report to the entire committee at a convened meeting identifying any significant changes, problem areas in need of modification, and areas in which the program is working particularly well.

Protocol Approval Period:
ASP's are approved for a period of three years. At the end of the three-year period, an ASP may be resubmitted as a new proposal and will be reviewed in the same manner as the initial animal study proposal.

Review of Contracts Involving Animals.
Contract Statements of Work are reviewed by the ACUC office and requests for clarification are sent to the contracting officer and COR. A designated member reviewer is assigned by the Chair. ACUC members are provided with the contract title and a brief description of the contract via electronic correspondence and are asked to respond within 24 hours if they wish for the submission to be reviewed by FCR. If full committee review is not requested the designated member has the authority to approve, require modifications to secure approval, or refer the submission to full committee for review. Actions taken are reflected in the ACUC meeting agenda and minutes. The date that the designated reviewer approves the SOW is considered the ACUC approval date. The CO is contacted in writing with the decision. (according to NIH PM 3040-3 Intramural Acquisitions Involving Animal Research Activities).

The following topics are considered during protocol preparation and review:

Investigator Training:
Investigators and all personnel using animals are required to complete the Humane Care and Use of Animals in Research at NIEHS training course. A T and E: Statement of Training and Experience for Use of Experimental Animals (T&E) for each participant must be submitted to the ACUC office. The forms are assessed during review of the protocol. If an investigator does not have documented experience with an animal procedure they will be instructed to work with the CMB Veterinary Medicine Section (VMS) to demonstrate proficiency. Training and proficiency is documented by VMS through a memo to the record and by updating the participants T&E. A refresher training course is also required every three years. Completion of training is verified during protocol review.

Safety Issues:
Health and safety permits for the use of hazardous agents (chemical, biologic or radioisotope) must be approved prior to ASP/amendment approval by the ACUC. The safety permit number is provided with the ASP. The safety permit is accessible online. No work involving rDNA and infectious agents may be initiated until approval is given by the NIEHS IBC.

Allocation of Space and Animal Resources:

These issues are outside the scope of the ACUC. CMB staff work with investigators to make resources available but in cases of shortage, these issues are resolved at the level of the Scientific Director.

NIEHS ACUC DEFINITIONS:

Animal

Any warm- or cold-blooded animal including invertebrates used in research at NIEHS must be covered by an approved Animal Study Proposal. In general offspring are considered to be "animals" at the time of birth. Avian species are considered to be "animals" at the time of hatching. Invertebrates are evaluated on a case-by-case basis.

Physical restraint:

Physical restraint is the use of manual or mechanical means to limit some or all of an animal's normal movement for such purposes as examination, collection of samples, drug administration, or experimental manipulation. Prolonged restraint is defined as physical restraint of a conscious animal in a normal postural position lasting longer than 20 minutes or restraining an animal in an unnatural position (i.e. dorsal recumbency) beyond the minimum needed for examination/sample collection/drug administration. Animals undergoing prolonged restraint should be acclimated to adapt to the equipment/personnel using positive reinforcement. Prolonged restraint should be avoided unless it is essential for achieving research objectives and is specifically approved by the ACUC.*4

Multiple Major Surgical Procedures

A major surgical procedure is defined as one that penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic function. Multiple major survival surgery on a single animal is discouraged and can be approved only when (a) the surgical procedures are related components of the research project, are justified for scientific reasons by the principal investigator in writing, and approved by the ACUC, or (b) required as routine veterinary procedures or to protect the health and well-being of the animal as determined by the veterinarian.

Exceptions to Guide Standards

Exceptions to The Guide are reviewed and approved by the ACUC, either during ASP/amendment review or during review of relevant ACUC policies or CMB SOP's. Guide exceptions are also documented during the semi-annual program review. Examples of exceptions that have been approved by the ACUC are reduced cage height of the Buxco system, cage capacity, gnotobiotic husbandry practices, and certain environmental conditions outside The Guide standards required by a scientific study.

NIEHS ACUC related FORMS include:

- Animal Study Proposal Form
- Amendment Form for Animal Study Proposals
- Statement of Training and Experience for Use of Experimental Animals Form (T&E)
- Justification for Column E Procedures Form

- Instructions for Conducting Literature Searches for Alternatives to Potentially Painful (Column D and E) Procedures

NIEHS ACUC Guidelines include:

- Summary of Acceptable Euthanasia Methods for Rodent Feti and Neonates, Adapted from the ARAC Guidelines for the Euthanasia of Rodent Feti and Neonates
- Guidelines for Feed Restriction
- Guidelines for Maintaining Animals in Laboratories
- Guidelines for Resolving Non-Compliance Issues
- Guidelines for the Estimation of Animal Numbers for Animal Study Proposals Involving Rodent Breeding
- Guidelines for Use of Controlled Substances
- Guideline on Determining Standard Nomenclature for Transgenic and Knockout Animals

NIEHS SOP'S include:

- Veterinary Medicine SOPs
  - Mouse SOPs
  - Rat SOPs
- ACUC SOPs that are relevant to NIEHS researchers

"The Humane Care and Use of Animals in Research" is also available in hard copy from CMB.

OTHER NIEHS ACUC REFERENCE DOCUMENTS

Are available at http://inside-dir.niehs.nih.gov/dircmb/restrictacuc/acuc.htm and Include:

- NIH Animal Research Advisory Committee (ARAC) Guidelines
  - *1ARAC Guideline Regarding Significant Changes to Animal Study Proposals
  - *2OLAW Guidance regarding IACUC Approval of Changes in Personnel involved in animal activities.

- US Public Health Service Policy on Humane Care and Use of Laboratory Animals, OLAW, August 7, 2002.

- Guide for the Care and Use of Laboratory Animals, Institute of Laboratory Animal Resources (ILAR), 2010

- US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training

- USDA Animal Welfare Act and Regulation
- USDA Animal Care Policies
- USDA AWA Briefs: A Quick Reference of the Responsibilities and Functions of the IACUC under the Animal Welfare Act
- NIH Manual Policy 3040-2 "Animal Care and Use in the Intramural Program"
- Manual Policy 3040-3 "Intramural Acquisitions Involving Animal Research Activities"
- NIH Animal Research Advisory Committee (ARAC) Guidelines
- Office of Laboratory Animal Welfare (OLAW) Institutional Animal Care and Use Committee Guidebook, NIH Publication No. 92-3415
- OLAW FAQs [3]
- AVMA Guidelines for the Euthanasia of Animals: 2013 edition
- Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition, December 2009
- Occupational Health and Safety in the Care and Use of Research Animals, NRC, 1997
- Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research
- NIH Manual Chapter 1743: Keeping and Destroying Records
- Kearns, R., Spencer, R. (2013). An unexpected increase in restrain duration alters the expression of stress response habituation. Physiology and Behavior, 122, 193-200.[4]
- Dhabhar, F, McEwen, B., Spencer, R. (1997). Adaptation to Prolonged or Repeated Stress- Comparison between Rat Strains Showing Intrinsic Differences in Reactivity to Acute Stress. Neuroendocrinology, 65, 360-368.[4]

Approved by NIEHS ACUC September 29, 2005
Revised and re-approved February 27, 2020

General Considerations:	A/M/S/C
Do you know the procedure for reporting animal welfare concerns (if you see something done to animals that may not be proper or correct)?	
Is a copy of the animal concern contact list posted/available? *Mention anonymous reporting and the website. Encourage all lab staff including students to be familiar with this process.*	
Do you know how to reach a vet after hours/in an emergency situation? Signs should be posted in the lab and info is available online at the CMB homepage.	
What training have lab personnel had in order to work with animals at NIEHS? *Humane care seminar, triennial refresher, proficiency check or one-on-one training with VMS (contact* Redacted by agreement Redacted by agreement *to coordinate)*	
What procedures are done in the lab? How often are they done?	
How long are animals in the lab? Labs should be used to house animals only when scientifically required and limited to minimum period necessary (Guide, p 134; ARAC Guideline C4)	
What are the procedures if you suddenly have to leave due to an emergency and cannot use the animals that day? *Place back in the home cage under a hood, call CMB vet.*	
If getting neonates without dam - are lab personnel aware of the one hour rule if neonates are present without dam under 14 days of age?	
Is there a copy of the ASP(s) posted or available on a nearby computer that all lab personnel can access?	
Are the lab personnel performing animal activities conversant with content of the ASPs?	
EUTHANASIA	
What method of euthanasia are you approved to use?	
Is dry ice used for euthanasia? *Should be 'no'*	
CO2	
If CO2 is used, are the instructions for use posted? Flow meter?	
Are other animals present during euthanasia? How do you handle if you're euthanizing multiple cages of animals? Maximize the distance between the cages. *Covered cages can be placed in the corridor or if you're in a large lab at a distance that would minimize the vocalization sounds.*	
How do you assure death? CD/thorocotomy	
Decap/CD without anesthesia	
If using decap /CD without anesthesia, discuss training and experience. *Must have been evaluated by VMS.*	
If a guillotine is present, has it been properly maintained? Clean and date sharpened? *Ensure blades are sharp by cutting in to a 2-3 mm rubber band without dragging the band BEFORE EACH USE.*	
If scissors used, are they sharpened and cleaned? *Ensure blades are sharp by cutting in to a 2-3 mm rubber band without dragging the band BEFORE EACH USE.*	
Controlled Substances	
Are controlled substances in-date and properly stored? Are appropriate records maintained? (Guide, pp 115, 122; NIH PM 1345)	
ANESTHESIA/SURGERY	
Describe surgical procedures and induction of anesthesia	

Who performs surgery in the lab? What training did personnel receive to perform the particular procedures.	
Where is surgery performed in the lab? *The surgery area should be clean and uncluttered, not used for anything else during surgery* (Guide, p 144)	
What PPE and prep is done? (from AAALAC PD " complete sterile technique is not required for non-survival procedures. At a minimum the surgical site is clipped, the surgeon wears gloves and the instruments and surrounding area are clean")	
How long is the surgery?	
How is anesthetic depth determined and monitored? *Palpepral and pedal reflex, respiratory rate*	
Are anesthetic gases scavenged approrpriately? Isoflurane is vented? *If using F/air check for weights and dates.*	
Have vaproizers been serviced/checked? If present, are O2 and CO2 tanks properly secured?	
Is body temperature maintained? How?	
Is an observer always present thorughout?	
Are peri-operative records available (species, surgery, monitoring reflexes [toe, palpebral], frequency (3-5min), document redosing of anesthetic). (Guide, p 120)	
What would be done in an emergency situation that occurs during a surgical procedure? *If no incision has been made, place the animal back in the home cage with food, water, and a cage top. If an incision has been made, euthanize the animal and evacuate the building.*	
FLEXIVENT	
Discuss the use of pralytics ("animals depth of anesthesia is assessed by lack of toe pinch and palpebral relex prior to administration of neuromuscular blocking agent. ECG, respiration and airway pressure are monitored continuously to ensure a deep level of anesthesia.")	
OCCUPATIONAL HEALTH	
Are workers enrolled in the NIEHS Occupational Health Monitoring Program?	
Is there periodic follow up by Occ Health?	
If hazards are used, is a safety protocol available that lab personnel are conversant with?	
Do lab personnel know how to report safety concerns or potential hazard exposures?	
Is apprpriate signage posted at the entry to the lab (ie. Biohazard, chemical hazard, animal allergy)	
Are sharps management practices and disposal appropriate? (Guide, p 74)	
Is apprpriate PPE available in the lab area (lab coat, gloves, mask)? *In order to minimize allergen exposure, animal procedures should be performed in a hood, if available, with personnel wearing a laboratory coat and gloves. Protective eyewear should be worn if a splash hazard is a possibility when working on an open benchtop. The addition of an N95 particulate mask will protect personnel working with animals on an open benchtop.*	
Site Visitor: Is there a possibility for exposure to others working in the lab?	
Biological Safety Cabinets (BSCs) and hoods are serviced annually with a sticker? *Grills/airflow not covered or impeded.*	
safety features (e.g., SOPs, safety signs, eyewash stations, showers, secure gas cylinders) are in place. Eyewash stations (weekly) & showers (yearly) are present, flushed at appropriate intervals & documented. (Guide, p 19 & p 143; NIH Chemical Hygiene Plan)	
WASTE/CARCASS DISPOSAL	
How is dirty caging returned to the facility? ASSURE cages are empty. Make sure cage cards are returned!	

carcass disposal (Guide, pp 73-74; NIH Waste Disposal Guide). Where? *Encourage* Redacted by agreement *but some will bring down to the animal facility freezers*	
Carcass disposal when bedding is hazardous: Follow specific SP procedures	
Ensure that dirty caging is reutrned the same day. *CMB is available to pick up.* Make sure cage lids are secure to limit allergen exposure.	

A = acceptable

M = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)

C = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

Notes from current visit: