



Institutional Animal Care and Use Committee (IACUC)

Policy and Procedures



Contents

Section I – Institutional Animal Care and Use Committee.....	4
[1 - 01] Roles and Responsibilities	4
[1-02] Appointment and Role of the Institutional Official	5
[1-03] IACUC Member Appointments and Training	5
[1-04] IACUC Member Training.....	5
[1-05] IACUC Meetings.....	6
[1-06] IACUC Meeting Minutes	6
[1-07] Reporting Mistreatment of Animals or Noncompliance Issues	6
[1-08] Allegations of Mistreatment or Protocol Noncompliance	6
[1-09] Determination of Corrective Actions/Sanctions	7
[1-10] Serious or Continuous Noncompliance Issues	7
[1-11] Minor Noncompliance Issues	8
[1-12] Requests for Reconsideration of Issues	8
[1-13] General Information	9
[1-14] Use of Electronic Mail (Email) for Official Correspondence	9
Section II – Protocol Review Process	10
[2-01] New Protocol applications	10
[2-02] Annual Reviews	12
[2-03] Modification Requests.....	12
[2-04] Addition of Personnel.....	13
Section III – Institutional Administrative Policies Regarding Animal Care and Use.....	14
Section IV – IACUC Policies.....	14
Appendix A – Addition of Personnel (SOP)	
Appendix B – Congruency Reviews (SOP)	
Appendix C – Animal Transfers	
Appendix D 1-3 – Animal Concern/Incident Reporting Forms	
Appendix E – Exporting Animals	
Appendix F – When an Animal Protocol May Be Required (guidance)	
Appendix G –Semiannual Program Review and Inspection (SOP)	
Appendix H – Post Approval Monitoring (SOP)	
Appendix I – Animal Holding Policy	
Appendix J – Enrichment Policy REDACTED See appendix N	
Appendix K – Social Housing Policy REDACTED See appendix N	
Appendix L – Needle Recapping Policy	
Appendix M – Overview of IACUC Process at Kent State	
Appendix N – Social Housing and Enrichment Policy	
Appendix O – Surgery (SOP)	
Appendix P – Tissue Transfer/Usage Form	
Appendix Q – Obtaining Project Renewals Standard Operating Procedure	



Appendix R – Manual Cage Sanitizing (SOP)

Appendix S – Minor Changes

Appendix T – Occupational Health Program for Persons Involved in Animal Care and Use

Appendix U – Tour Request *Under Further IACUC Review*

Appendix V – Drugs and Chemicals Used in Animals (guidance)



Section I – Institutional Animal Care and Use Committee

[1 - 01] Roles and Responsibilities

The Institutional Animal Care and Use Committee (IACUC) at Kent State University has been established to implement the University's commitment to assuring humane care and use of animals in research and education. The IACUC operates in accordance with the United States Public Health Service (PHS) policy on humane care and use of laboratory animals, the PHS "Guide for the Care and Use of Laboratory Animals," the provisions of the United States Animal Welfare Act, and other applicable laws and regulations.

The IACUC has the following responsibilities:

1. Review at least once every six months, the university's program for humane care and use of animals and ensure compliance with state and federal regulations.
2. Inspect the University animal facilities at least once every six months, using "The Guide" as a basis for evaluation, to ensure facilities meet established guidelines and regulations.
3. Prepare and submit reports of the semi-annual facility inspection and program evaluations to the Institutional Official.
4. Provide assistance and guidance on research involving animals. Make recommendations to the Institutional Official regarding any aspect of the university's animal program.
5. Implement University guidelines and state and federal regulations in all aspects of the humane care and use of animals.
6. Review and approve, require modifications, or withhold approval of all research protocols and changes to on-going protocols involving the use and care of animals.
7. The IACUC shall conduct continuing review of all previously approved research protocols at appropriate intervals, as determined by the committee, but not less than annually.
8. The IACUC shall review and investigate any concerns regarding the care and use of animals.
9. The IACUC is authorized to suspend an activity involving animals, if that activity is not being conducted in accordance with the applicable provisions of the Animal Welfare Act, the PHS Guide, the institution's Assurance, or the PHS Policy.
10. Ensure that all personnel involved with animal care, treatment or use are adequately trained and/or experienced in the humane care and use of animals and the occupational health and safety programs associated with the use of animals in research.

The Research Compliance office is responsible for the maintaining of the following records:

- ❖ Office of Laboratory Animal Welfare (OLAW) Assurance documentation.
- ❖ Minutes of IACUC meetings.
- ❖ Records of IACUC activities and deliberations.
- ❖ Minority IACUC views.
- ❖ Documentation of protocols reviewed by IACUC, and proposed significant changes to protocols.
- ❖ IACUC semiannual program evaluations and facility inspections, including deficiencies and identified plans for correction.
- ❖ Accrediting body reports, and determinations.



- ❖ USDA reports, and determinations.

Access to the offices where records are kept is restricted to designated personnel and the rooms are secured when the staff is absent.

[1-02] Appointment and Role of the Institutional Official

The Kent State University Provost appoints and approves the Institutional Official (IO).

The IO is the individual who is authorized to legally commit on behalf of the research facility that it will meet the requirements of the Animal Welfare Act Regulations (AWAR). Similarly, PHS Policy defines the IO as the individual who signs and has the authority to sign the institution's Assurance, which commits the institution to meet the requirements of the PHS Policy. The IO is the individual who is responsible for ensuring that an institution complies with all applicable animal welfare laws, regulations, and policies. The IO signs forms, reports, and letters on behalf of the institution, and interacts with the IACUC in overseeing the institution's animal care and use program. The IO appoints the Chair of the IACUC.

[1-03] IACUC Member Appointments and Training

According to the PHS Policy on the Humane Care and Use of Laboratory Animals, the IACUC must consist of not less than five (5) members, and shall include at least one (1) Doctor of Veterinary Medicine with training or experience in laboratory animal science and medicine, one (1) practicing scientist experienced in research involving animals, one (1) member whose primary concerns are in a nonscientific area, and one (1) individual who is not affiliated with the institution in any way other than as an IACUC member.

IACUC members are appointed by the Institutional Official/Vice President for Research and are charged with assessing the institution's animal care program, facilities and procedures based upon their education, experience, and expertise. The IACUC at Kent State University includes a chair, an attending veterinarian, a non-affiliated member, experienced scientists and researchers, faculty, and staff.

[1-04] IACUC Member Training

IACUC members complete a training course developed by, and under the direction of, Dr. Walter Horne, University attending veterinarian. The training provides an overview of PHS and USDA policies/regulations, Standard Operating Procedures for laboratory safety practices, and IACUC functions and requirements. In addition to the training, IACUC members receive training from the IACUC administrator regarding KSU University policies and procedures for reviewing protocols. Each committee member is provided:

- A copy of *The Guide for the Care and Use of Laboratory Animals*
- A committee roster
- Information regarding meeting dates – also available on Research website
- Sample protocol form

[1-04.1] Additional Support



IACUC members can meet with either the Chair or the attending veterinarian with any additional questions that they may have.

[1-05] IACUC Meetings

The IACUC meets on the second Monday of each month unless cancelled by the IACUC chair, or a member of the Research Compliance office staff under direction from the IACUC chair. A meeting quorum consists of one more than half of the regular IACUC voting members. These meetings are closed sessions with attendance limited to only members of the IACUC, Research Compliance staff members, investigators whose protocols are being reviewed, and other persons adding expertise on the issues of concern.

[1-06] IACUC Meeting Minutes

IACUC meeting minutes are recorded and maintained by the Research Compliance office and are made available for review to the pertinent regulatory agencies, as required.

- Minutes are taken at the meeting and are as inclusive as possible to record the true breadth of discussion by the IACUC.
- Minutes shall include the time of the meeting and those members present.
- All votes are recorded in the minutes listing number for, against and abstaining, along with major discussions and any conditions for approval.
- Minutes from the previous meeting are included with the Agenda for IACUC members to review.
- Any corrections/comments needed to the minutes are noted in the minutes of the next meeting.
- The minutes are corrected accordingly and are then considered final.
- Copies of the finalized minutes are posted to the Research Compliance server and/or website shared only with IACUC members.
- Distribution of the minutes is limited to the IACUC, the Institutional Official, accrediting bodies and regulatory agencies charged with federal oversight responsibilities for animals used in laboratories.

[1-07] Reporting Mistreatment of Animals or Noncompliance Issues

The Administration of Kent State University advocates the finest animal care and assures the public, researchers, employees and students that there is a true desire to investigate allegations of mistreatment or noncompliance. The IACUC and veterinary staff fully support this philosophy. Under no circumstances will reporting such instances be detrimental to an individual's standing within the University as this action is protected under the law (9CFR, Part 2, Subpart C 2.32 (c)(4)).

Staff and researchers working in the animal facilities are instructed to report all incidents of non-compliance with regulatory standards of animal care and use to the facility supervisors or managers, IACUC Chair, IO, and Attending Veterinarian. Non-compliance may take on many forms, including but not limited to, mishandling of animals, inappropriate housing, deviation from an approved protocol, etc.

[1-08] Allegations of Mistreatment or Protocol Noncompliance

All reports of concerns involving the care and use of animals will be immediately distributed to the IACUC Chair, Departmental Chair, and University attending Veterinarian. At least two representatives of the IACUC including the University Veterinarian, or a designate, will investigate the allegation as soon as possible to determine the immediate



health and well being of the animals. Allegations related to biological, chemical, or radiological safety are reported to the Office of Research Safety and Compliance. Deficiencies compromising the immediate health and welfare of the animals will be remedied immediately by representatives of the IACUC and deficiencies compromising the immediate health and well being of the humans will be remedied immediately by the appropriate University official. Following investigation of the animal's welfare and/or human occupational health and safety, the IACUC and IO will thoroughly investigate all aspects of the allegation and prepare a written incident report. The incident report will be submitted to the IACUC for review and discussion. If a follow-up meeting is required the investigator will be invited to attend and the objectives of the meeting are to:

- Review the incident report and discuss the allegations with the investigator(s) involved
- Substantiate the validity of the allegation by a majority opinion of the IACUC
- Record a listing of noncompliance issues
- Record all minority opinions of the noncompliance issues
- Record a listing of corrective actions/sanctions for the investigator
- Record all minority opinions of the recommended corrective actions/sanctions
- Decide on the response to the originator of the allegation

The minutes of the IACUC meeting will record these objectives.

The Research Compliance Office will send a letter on behalf of the IO to the investigator describing the noncompliance issues and the required corrective actions/sanctions, with related deadlines, prescribed by the IACUC. The letter will also inform the investigator of his/her option to appeal the decision by writing the IACUC Chair within 10 days of receipt of this letter, detailing the basis of the appeal and requesting a meeting with the IACUC. There may be circumstances in which the corrective actions/sanctions imposed by the IACUC will continue at least through the time that the matter is finally resolved.

The IACUC Chair will copy all noncompliance letters to the IO and Departmental Chair of the investigator. The IO, in consultation with the IACUC, may impose further corrective actions/sanctions for the investigator. The Research Compliance office will inform the originator of the allegation of the IACUC's disposition of the allegation.

[1-09] Determination of Corrective Actions/Sanctions

All issues reported to Kent State University IACUC involving known, or suspected noncompliance with federal regulations and /or IACUC requirements or determinations governing animal research shall be submitted for review by the IACUC as described in Section 1-07. If the IACUC, by majority vote, finds that the allegations, have merit and represent noncompliance the following guidelines are to be used to determine corrective actions/sanctions:

[1-10] Serious or Continuous Noncompliance Issues

Acts of noncompliance are deemed serious if they can or do affect the health, safety or well being of animals or personnel. If the IACUC by a majority vote determines that the reported problem represents serious or continuing noncompliance with federal regulations and/or IACUC requirements or determinations it may, in consideration of the nature of the research study and the reported problem institute one or more of the following sanctions:

- Termination of the IACUC approval of the respective research study after consultation with the IO.



- Suspension of the IACUC approval of the respective research study pending completion and acceptance by the IACUC of an independent audit of the study and/or the submission, by the principal investigator, of a written plan for the correction and/or prevention of the problem.
- Suspension of further animal orders for the research study pending completion and acceptance by the IACUC of an independent audit of the study and/or the submission, by the principal investigator, of a written plan for the correction and /or prevention of the problem.
- Other action as the IACUC deems appropriate.

The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description of that activity provided by the principal investigator and approved by the Committee. If the IACUC decides to suspend or terminate the approval of a research study, this decision and the reason(s) for this decision will be reported, within one week of the IACUC decision, to the Institutional Official, OLAW, and if applicable, the USDA, any Federal agency funding the study, and the department Chair.

[1-11] Minor Noncompliance Issues

Acts of noncompliance are deemed minor if they do not affect the health, safety or well being of animals or personnel. If the IACUC determines that the reported problem represents a minor noncompliance with federal regulations and/or IACUC requirements or determinations it may, in consideration of the nature of the research study and the reported problem take one or more of the following actions:

- Elect to make corrective action only.
- Provide a verbal and/or written listing of the issue of noncompliance to the investigator and require a corrective action plan at a regular meeting of the IACUC and recording this incident in the IACUC minutes.
- Provide a written listing of the issue of noncompliance to the investigator requiring a corrective action plan within a specified time period. The letter may or may not be copied to the investigator's department Chair depending on the IACUC's decision.
- Other action as the IACUC deems appropriate.

[1-12] Requests for Reconsideration of Issues

The procedure for request for reconsideration of any IACUC issues is as follows:

1. The PI of the study must submit in writing to the IACUC the details and rationale of the request within ten (10) days of being notified of the IACUC's decision.
2. A representative from the Research compliance Office or the IACUC will acknowledge receipt of the letter in writing and forward a copy to the IACUC Chair and University veterinarian.
3. The IACUC Chair will decide if the issue requires full committee review, or if it can be addressed by a subcommittee.
4. The PI will be informed of the decision and may be asked to appear before either the full committee or the subcommittee to discuss the concerns.
5. Following the discussion of concerns, the IACUC or subcommittee will meet to reconsider the issue.



6. A written record of the discussion and reconsideration meetings will be made.
7. A summary of the written record along with the IACUC's reconsideration decision will be sent to the PI and the Institutional Official.
8. The Institutional Official will meet with the IACUC or subcommittee for further discussion if warranted.
9. A written record will be made of the meeting between the IACUC and the Institutional Official, and a summary will be provided to the PI along with the final decision on the issue.

[1-13] General Information

If the IACUC decides to withhold approval of an activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the IACUC-approved protocol. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.

If the IACUC suspends an activity involving animals, the IO in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW.

[1-14] Use of Electronic Mail (Email) for Official Correspondence

Electronic mail (email), like postal mail, is a mechanism for official University communication. The IACUC will exercise the right to send email communications to all laboratory animal users and the IACUC will expect that email communications will be received and read in a timely manner.

This policy applies to all faculty, staff, students, or any other person listed on a Request to Use Animals submitted to the IACUC for review and approval. Official communications using email can include email to a group, or an email message to only one person.



Section II – Protocol Review Process

The IACUC is responsible for assuring that the research, husbandry, teaching and testing programs involving animals at Kent State University provide for animal welfare and comply with all applicable regulations and policies. To fulfill this responsibility, the IACUC reviews *all* animal research and testing procedures. No animal experimentation, or use is permitted at Kent State University without written approval by the IACUC. As such, all animal users at Kent State University must complete the Request to Use Animals protocol application, which can be obtained from the IACUC website (<http://www.kent.edu/research/researchsafetyandcompliance/iacuc/forms>).

Currently, the protocol application is in the form of an MS Word template investigators download and completes on their computer. Periodically, the IACUC reviews and/or changes the application, investigators must be sure to use the most recent form.

- Only full-time faculty, students, or staff may serve as principal investigator on Kent State University IACUC protocols.

[2-01] New Protocol applications

According to the Public Health Service (PHS) guidelines, protocols can only be approved for a three (3) year period, after which the investigator is required to submit a new protocol in order to continue the project. In order to comply with these guidelines and the requirements of the Animal Welfare Regulations (AWR), the IACUC will review all protocols annually through the use of an annual review form and require a new protocol submission every three years. The IACUC Coordinator will notify the investigator when annual protocol updates are needed and/or when a protocol is approaching the expiration of its 3-year approval limit.

Investigators are advised that because Kent State is a state institution, all protocols, annual reviews, modification requests, and related paperwork are considered public documents. Hence, this paperwork is subject to the Ohio Open Records laws.

1. The Principal Investigator (PI) sends the application to the Research Compliance office as an email attachment. The PI should save an electronic copy for their files.
2. The Research Compliance office assigns a protocol number to the application and within 1-2 business days, sends an email to the PI confirming that the office has received the application, and informs the PI of the number assigned to the protocol for use when corresponding with the Research Compliance office about the protocol.
3. Protocol information is entered into a database to maintain compliance records and to accommodate the requests for information from AAALAC, Office of Laboratory Animal Welfare (OLAW), the US Department of Agriculture (USDA) and any other regulatory or internal requests.
4. The coordinator reviews the protocol for overall completeness/accuracy and ensures that all required training for the protocol has been completed for the PI, and each additional individual listed as personnel on the protocol. The coordinator will notify the Investigator of any training/testing requirements that have not been



completed by the individuals listed on the application.

5. The Research compliance office returns the application to the Investigator if the application is incomplete, or if there are any questions that need to be addressed before the application can be sent to the IACUC reviewers.
6. The protocol is distributed via email to all members of the IACUC. Three of the members are specified as designated reviewers for the protocol: the IACUC chair, the attending veterinarian, and an IACUC member. The IACUC member reviewer is rotated among the membership on a monthly basis. IACUC members have seven days to review the protocol and communicate any concerns. Any IACUC member can request a full committee review of the protocol by contacting the research coordinator. The protocol review takes place at the next scheduled IACUC meeting. The PI is asked to attend the meeting to address any questions/concerns from the IACUC.

Pain category “E” (pain or distress which are not relieved by analgesia, anesthesia, or tranquilization) protocols must always be reviewed at a fully convened IACUC meeting. Protocols reviewed at a fully convened meeting must be approved by a quorum of the IACUC.

Protocols are assessed for:

- **Federal Criteria for Granting IACUC approval**
- **Activities** – Must be in accord with USDA regulations/PHS policy.
- **Pain/Distress** - Must avoid/minimize discomfort/distress/pain. If pain/distress is caused, appropriate sedation, analgesia or anesthesia will be used unless scientifically justified. Attending Veterinarian must be involved in planning. Use of paralytics without anesthesia is prohibited. Animals with chronic/severe unrelieved pain will be painlessly euthanized.
- **Surgery** – Must meet requirements for sterile surgery and pre/post operative care. Cannot use one animal for several major operative procedures from which it will recover, without meeting specified conditions.
- **Euthanasia** – Method must be consistent with USDA and Public Health Service regulations.
- **Housing/Health** - Animal living conditions must be consistent with standards of housing, feeding and care directed by veterinarian or scientist with appropriate expertise.
- **Alternatives** - There must be considered alternatives to painful procedures; also must document consideration of alternatives if animals experience pain or suffering.
- **Rationale and Methods** - Must provide written narrative of methods/procedures performed on all animals and a rationale for any painful/distressful procedures.
- **Duplication** - Must provide assurance that activities do not unnecessarily duplicate previous efforts.
- **Qualifications** - Personnel must be appropriately qualified and trained.

If a request is not made by an IACUC member for full committee review the protocol will be approved through the designated review process. The comments/concerns from the three designated reviewers are compiled by the research Coordinator and sent to the principal investigator via email. The PI is asked to revise the protocol according to the reviewer comments and resubmit it electronically to the Coordinator. Responses to IACUC committee concerns **must be highlighted in yellow**. The PI should keep a revised electronic copy for their files.



This process repeats until approval is obtained from each of the three designated reviewers. The PI will be asked to obtain the necessary signatures and send the scanned signature pages via email to the IACUC Coordinator. The signed Investigator Assurance and Participant Qualification pages are needed for final IACUC approval.

7. The approval for the protocol is communicated to the investigator via email, and the IACUC committee is notified of the approval at the next convened meeting.

[2-02] Annual Reviews

Annual reviews of ongoing protocols are conducted through an administrative review process unless a regulatory, animal welfare, or other operational issue, whether newly discovered or historical, requires or demonstrates the need for designated member or full committee review. The administrative review process can be conducted by any member of the IACUC.

Investigators are responsible for obtaining annual review approval by the annual review date assigned by the IACUC for protocols covered by the Animal Welfare Act (USDA species) or as dictated by other regulations, including the DoD. Protocols may go through no more than two annual reviews; a de novo review is required for all projects extending beyond three years.

The PI is notified via email of the IACUC's decision regarding the approval status. The approved annual review, with any reviewer comments, is filed with the original protocol. The IACUC is notified of all annual reviews via a subsequent agenda. Inclusion on an agenda permits the IACUC the opportunity to seek additional information should an issue not be identified during administrative review process.

[2-03] Modification Requests

A Modification Request must be submitted when a change or addition to the protocol is proposed. These changes may include, but are not limited to:

- the species used.
- numbers of animals needed.
- experimental and/or surgical procedures to be performed, etc.

Changes must be approved by the IACUC before they are implemented. Modification Requests are to be submitted electronically to the Research Coordinator. The PI should save an electronic copy for their files. If there are frequent modifications to a protocol, the IACUC may require submission of a new protocol.

The Modification Request and the protocol are forwarded via email to each IACUC member. Three of the members are specified as designated reviewers for the protocol: the IACUC chair, the attending veterinarian, and an IACUC member. IACUC members who are not serving as designated reviewers have five working days to request full board review. Any reviewer comments will be forwarded to the PI via email. If revisions are indicated, the PI will be asked to submit a revised form as an email attachment to the Coordinator. Revisions are to be indicated with yellow highlighting. The PI will be asked to print, sign, scan, and send the signature page to the Coordinator via email.

IACUC members have seven days to review the Modification Request and communicate any additional concerns. Any IACUC member can request a full committee review of the modification by contacting the Research Coordinator. The



review would then take place at the next scheduled IACUC meeting. If no additional concerns are communicated, the designated reviewers send their approvals via email and then sign the Modification Request indicating final IACUC approval at the next scheduled IACUC meeting. The PI is notified in writing via email of the IACUC's decision regarding the approval status of the Modification Request. The approved Modification Request, with any reviewer comments, is filed with the original protocol.

[2-04] Addition of Personnel

The Add Personnel form is used to designate new personnel (including technical support, graduate students, student volunteers, etc.) who will participate on the protocol. New personnel must participate in the IACUC-approved "Introduction to Laboratory Animal Care" web-based course and also complete the necessary occupational health and safety program requirements.

Personnel must indicate their training and/or experience with procedures relevant to those described in the protocol. It is acceptable to include a statement that personnel will be trained by the investigative staff in those procedures relevant to the protocol. By signing the form, participants acknowledge that they have read the protocol and agree to comply with it.

The completed form is sent to the IACUC Coordinator for processing. At the next IACUC meeting, the form is circulated among three IACUC representatives (IACUC chair, attending Veterinarian, and animal facility director/supervisor) for their review and signature. A list of added personnel is appended to the IACUC meeting agenda to notify all members of the IACUC. If there are questions regarding the qualifications and/or training of the personnel for a protocol, the Research Coordinator communicates the question(s) to the PI and/or personnel involved and follows up to the IACUC members via email until all are in agreement that final approval can be granted. The approved Add Personnel form is added to the original protocol file. The PI is notified via email of the IACUC's decision regarding the approval status of the Add Personnel form.

[2-05] Protocol Termination Forms

Termination will be emailed to the PI approximately 45 days before the expiration date of the 3rd anniversary of the original protocol approval dates.

If the protocol will not be continuing the PI needs to:

1. Complete Section 1 (Project Status) and Section 3 (Protocol Deviations or Adverse Events).
2. Save the form and then print, sign, and scan the completed form to the IACUC coordinator via email by the "Submit by" date. The PI should keep an electronic copy for their files.

If the protocol is continuing and use of animals is continuing without interruption it is not necessary to submit a termination form. However, investigators are responsible for receiving approval of a new Request to Use Animals (see 2-01) form prior to the protocol's expiration date. Failure to receive approval of a new protocol will result in all animals being transferred to the Holding Protocol.



If the protocol will be renewed and animal use not active at the time of protocol expiration the submission of a termination form is acceptable so long as no animal use occurs until a newly approved Request to Use Animals form is obtained.

Section III – Institutional Administrative Policies Regarding Animal Care and Use

Kent State University Policy (10-02.2) of the official Register lists the administrative policies regarding animal care and use.

This policy can be found at the following website: <https://www.kent.edu/policyreg/chapter-10-research-sponsored-programs>

Section IV – IACUC Policies

The following is a list of IACUC guidelines/policy statements. This is not a comprehensive list as the Office of Research Compliance is currently in the process of developing and standardizing the policy statements. Please contact the IACUC Chairperson, attending veterinarian, or Office of Research Compliance staff should you have any questions regarding procedures or policy related to laboratory animal use or care. For contact information, visit the research website.

[4-01] Training for lab personnel in decapitation or cervical dislocation - If animal decapitation or cervical dislocation procedures are being utilized it is the responsibility of the principal investigator to ensure that lab personnel are adequately trained in the proper techniques for this process. Upon training, lab personnel must demonstrate the procedure to a qualified IACUC member and training/approval should be notated on the “Addition of Personnel” form.

[4-02] Changes in personnel on an approved protocol - The Kent State University IACUC requires that changes in personnel be reported with the submission of an “Addition of Personnel” form.

[4-03] Changes in protocol design, procedures, or animals - A change in protocol design, procedures, or animals requires the submission and IACUC approval of a “Modification Request to Use Animals” form.

[4-04] Decapitation and Cervical dislocation - Manual cervical dislocation is a humane technique for euthanasia of poultry, other small birds, mice, rats weighing < 200 g. can be classified as pain category C.

[4-05] Animal Care and Use Online Training – must be completed before final IACUC approval is received for an animal protocol.

[4-06] Online Occupational Health and Safety training – revised November, 2016. See Occupational Health Program for Personnel Involved in Animal Care and Use.

[4-07] Literature Searches – must be documented to occur within the last 30 days before submission of a Request to Use Animals application.

[4-08] Use of Animal Tissue obtained from animals not covered by a KSU IACUC approved protocol – revised April 2016. See When an Animal Use Protocol May or May Not be Required and Supporting Tissue Transfer/Usage Form



[4-09] *The applications (IACUC Forms) are used by the IACUC to evaluate the research with respect to the care and treatment of animals. It is also used by various regulatory agencies (e.g., the USDA) to evaluate the compliance of the institution with the various policies and regulations. Therefore, investigators are required to complete all sections of the IACUC forms according to the instructions on them, and in so doing, provide all the information necessary to all these purposes. Failure to include required information can result in delays for gaining IACUC approval (October 10, 2011).*

[4-10] *New procedure for conducting congruency reviews between IACUC protocols and grant applications (minutes, February 13, 2012).*

[4-11] *A new form for the transfer of animals from one protocol to another was developed (minutes, August 13, 2012).*

[4-12] *A procedures and form were developed for exporting animals from KSU animal facilities (minutes, August 13, 2012 and January 14, 2013).*

[4-13] *A policy for the restraint of animals was developed (minutes, July 22, 2013).*

Prolonged restraint (>15 minutes) OR restraint that is utilized to induce stress as part of the experimental paradigm must be documented in the IACUC Protocol.

Prolonged restraint may be stressful to the animal and should be avoided unless essential to the research objectives. When restraint is required, consideration should be given to using the least restrictive method possible independent of economic or technical constraints. If prolonged restraint is required, the following procedures must be used.

- Animals to be placed in restraint equipment should be conditioned to the equipment by gradually increasing times of restraint until the maximum restraint time is reached.
- The period of restraint must be limited to the minimum required to accomplish the research objectives.
- For comfort and safety of the animal, certain types of restraint equipment, such as slings for dogs, require that the animals be attended throughout the period of restraint. For each situation, the IACUC will make a determination as to the intensity of the attention required.
- Restraint utilized as a method of inducing animal stress is a well-established model. Protocols requesting restraint stress must scientifically justify the need for such and minimize the stress period to that which is scientifically justified. Restraint devices should be designed for rodents so that they cannot injure themselves. Criteria for timely intervention if distress develops should be addressed in the protocol.

[4-14] *A policy regarding pilot studies was developed (minutes, July 22, 2013).*

When novel studies are proposed or information for an alternative endpoint is lacking the use of a pilot studies is an effective method for identifying and defining humane endpoints and reaching consensus among the PI, IACUC, and AV. All pilot studies must be approved by the IACUC. When necessary the IACUC /AV/Chair may request the study's PI to communicate in writing any significant findings that relate to the health and welfare of animals.

[4-15] *A policy on toe-clipping was developed (minutes, July 22, 2013).*

This method of identification should only be used when no other individual identification method is feasible. Scientific Justification is required if this procedure is performed. Under all circumstances aseptic practices should be followed. When possible, this method of identification and genotyping should be combined. Toe-clipping without anesthesia is limited to rodents within the first week of life (7 days) and must be limited to one digit per animal. General anesthesia must be used for toe-clipping of mice older than one week. The recommended age range to toe clip pups is 4-7 days.



[4-16] A policy on seeking veterinary consultation when the anticipated pain or distress level is exceeded was developed (minutes, July 22, 2013).

Veterinary consultation must occur as soon as possible when pain or distress is beyond the level anticipated in the protocol description or when interventional control is not possible.

[4-17] A Procedure for Reporting IACUC-Approved Exceptions to the Regulations and Standards to the USDA was developed (minutes, July 22, 2013).

Multiple major survival surgical procedures on a single animal must be clearly described in the animal protocol and approved by the IACUC. Scientific justification must be provided. **USDA Regulated Species:** The Institutional Official must submit a request to the USDA/APHIS and receive approval in order to allow a regulated animal to undergo multiple major survival surgical procedures in separate unrelated research protocols. See USDA Guidance for procedures.

Definitions:

Pharmaceutical grade compound: A drug, biologic, reagent etc. which is approved by the Food and Drug Administration (FDA) or for which a chemical purity standard has been written/established by United States Pharmacopeia (USP), National Formulary (NF), or British Pharmacopeia (BP).

Steps 1 and 2:

- Complete the Online Occupational Health and Safety Program
 - <https://sites.google.com/a/kent.edu/division-of-research-and-sponsored-programs-intranet/home/office-of-research-compliance/iacuc/training>
- Complete CITI Animal Care and Use Training
 - <https://www.citiprogram.org/>



Step 3:

Access and complete the Addition of Personnel form available at:

- <https://sites.google.com/a/kent.edu/division-of-research-and-sponsored-programs-intranet/home/office-of-research-compliance/iacuc/iacuc-forms>
 - ➔ Submit it to researchcompliance@kent.edu (recommended) or via campus mail



Step 4:

After the form is received by Research Compliance it is reviewed to ensure that all participants have completed the required programs-Steps 1 and 2. If these steps have not been completed the P.I. and the participant will receive an email notifying them of the need to complete these requirements.



Approval

The P.I. is sent an email approving the newly added participant and that individual may work on the protocol.



The IACUC is notified of all Addition of Personnel by inclusion with meeting materials. The IACUC will acknowledge but does not need to approve Addition of Personnel.



Disapproval

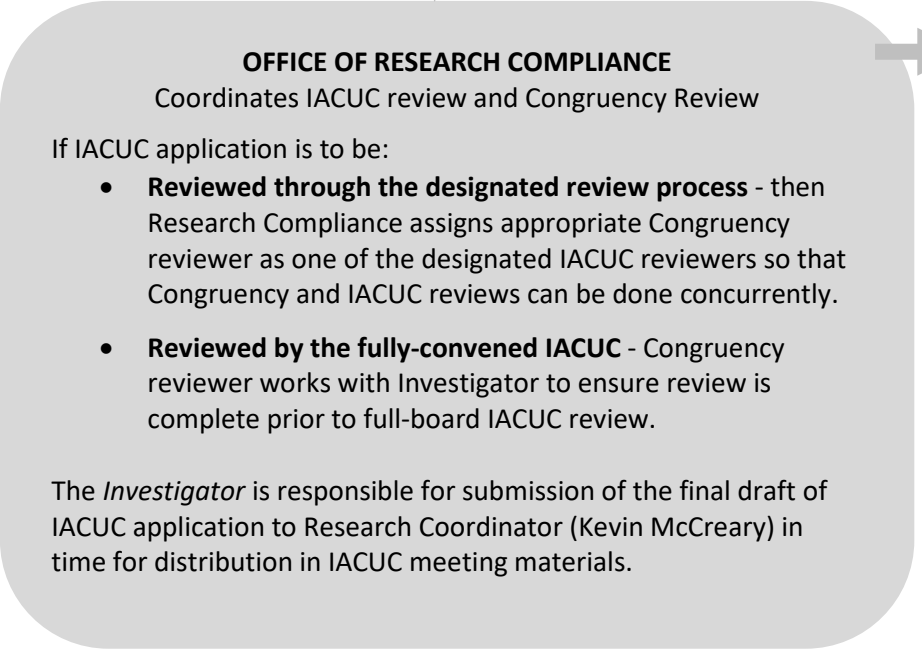
- It was determined that some area of the Addition of Personnel form is insufficient.
- The concern is forwarded via email to the P.I.
- Steps 3, 4 and 5 must be repeated until approval is received.

Why does a congruency review need to be done?
[PHS Policy](#) and the NIH Grants Policy Statement ([Part II, Terms and Conditions](#)) require the institution to verify, before award, that the IACUC has reviewed and approved those components of grant applications and contract proposals related to the care and use of animals.

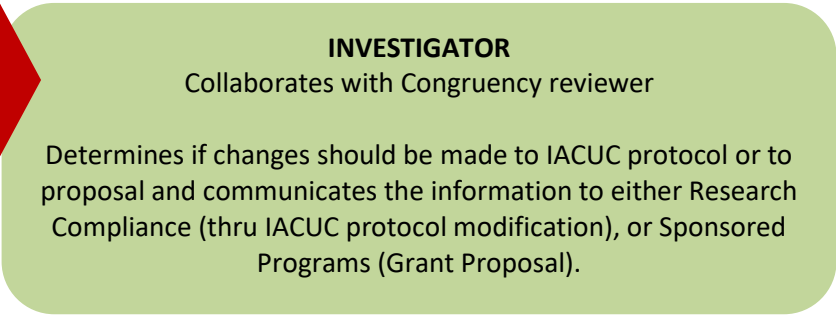
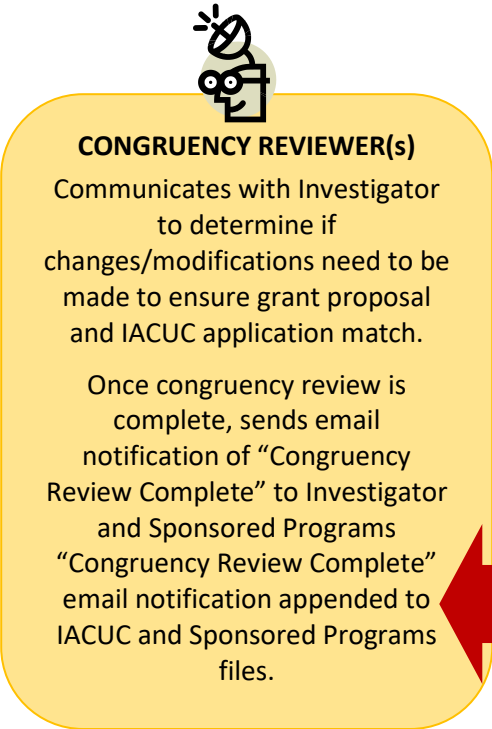
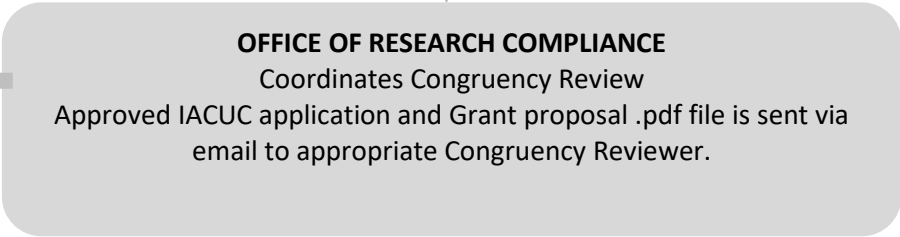
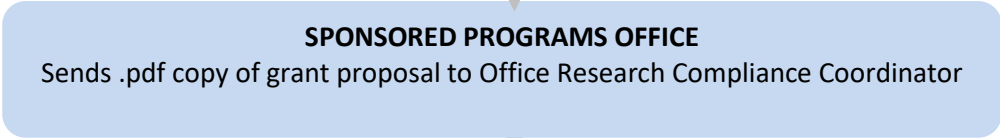
GRANT PROPOSALS THAT INVOLVE THE USE OF ANIMALS



PROJECT **DOES NOT** HAVE “IACUC APPROVED” ANIMAL USE PROTOCOL



PROJECT **HAS** AN “IACUC APPROVED” ANIMAL USE PROTOCOL



ANIMAL TRANSFER FORM

The transfer of animals from one protocol to another must be tracked for animal usage. Please complete this form in its entirety and return to appropriate facility personnel and the Research Compliance Office. ***NOTE: Any animals used in Category "E" Procedures (as described in the "Request to Use Animals" form), may not be transferred to any other protocol.***

Written verification of IACUC approval will be electronically forwarded to all involved parties. The CMU staff will make the necessary transfers on all associated paperwork.

DONOR PROTOCOL INFORMATION:

PI Name (Donor):	
PI (Donor) Protocol #:	
Species Being Donated:	
# of Animals Transferred:	
Current Animal Room #:	
Procedure(s) Performed on Animals(s):	

Signature, Donor PI

Date

RECIPIENT PROTOCOL INFORMATION:

PI Name (Recipient):	
PI (Recipient) Protocol #:	
Specific Procedure(s) to be Performed on the Animals(s):	

I verify that the animals being transferred to my name will be used in accordance with the previously approved procedures listed in my protocol # identified above. I further verify that animals used in any pain or distress procedures on the donor protocol will not be subjected to any other pain or distress producing procedure unless it is performed under complete surgical anesthesia from which the animal will not recover:

Signature, Receiving PI

Date

Signature, IACUC Chair

Date



Notification of Report of Concern Regarding Animal Welfare

Instructions:

The Kent State University Institutional Animal Care and Use Committee (IACUC) provides a means whereby personnel involved in the care and use of animals in research can report any potential areas of concern and allegations of noncompliance about animal welfare. An incident of concern may take on many forms, including but not limited to, mishandling of animals, inappropriate housing, deviation from an approved protocol, etc.

Complete this form within 14 days of receipt to respond to a report or concern involving the welfare of animals used in research.

GREY SHADED AREAS FOR USE BY OFFICE OF RESEARCH COMPLIANCE (ORC)

Date of Report:

IACUC Protocol (if applicable):

Reported Concern(s):

Response from Principal Investigator (PI):

Please provide your response to the above communicated concern in the area below. If applicable, provide insight for the factors that may have contributed to the concern and your plans for future avoidance of this issue.

Were these activities PHS supported?

☐ Yes ☐ No

If yes, Sponsored Programs Proposal Number:

Electronic Signature of PI:

Note: This form must be submitted from the Principal Investigator's @kent.edu email account.

IACUC Meeting Date:

Upon review at a fully-convened meeting, the IACUC made the following determination:

- ☐ Recommendations for corrective actions
- ☐ Dismissal of concern (i.e., unsubstantiated claim)
- ☐ Further investigation by an IACUC subcommittee
- ☐ Modification to animal use protocol
- ☐ Education or training for PI and/or research staff
- ☐ Monitoring of animal use activity
- ☐ Suspension or termination of IACUC approval
- ☐ Referral to other university process (e.g., misconduct review)

Initial Report to OLAW (if applicable):

Final Report to OLAW (if applicable):

OLAW Findings (if applicable):

Details:



Notification of Report of Concern Regarding Animal Welfare

Instructions:

The Kent State University Institutional Animal Care and Use Committee (IACUC) provides a means whereby personnel involved in the care and use of animals in research can report any potential areas of concern and allegations of noncompliance about animal welfare. An incident of concern may take on many forms, including but not limited to, mishandling of animals, inappropriate housing, deviation from an approved protocol, etc.

Complete this form within 14 days of receipt to respond to a report or concern involving the welfare of animals used in research.



Reports of Concerns and Investigations Involving Animal Care and Use

Definitions

Noncompliance – failure (intentional or unintentional) to comply with applicable federal regulations, state or local law, requirements or determinations of the IACUC, or university policies regarding research or teaching involving animals.

Allegation of noncompliance – an unconfirmed report of noncompliance.

Overview

The Kent State University Institutional Animal Care and Use Committee (IACUC) provides a means whereby personnel involved in the care and use of animals in research can report any potential areas of concern and allegations of noncompliance about animal welfare. An incident of concern may take on many forms, including but not limited to, mishandling of animals, inappropriate housing, deviation from an approved protocol, etc.

Reports of concerns regarding the welfare of animals used in research that arise (regardless of where they originate, i.e., internal or external) shall be communicated to the Office of Research Compliance (ORC). The ORC shall process reports in accordance with this policy.

Concerns or allegations of noncompliance issues regarding animal welfare shall remain confidential to the extent permitted by Ohio law, consistent with the need to conduct an adequate investigation. In accordance with the KSU Whistleblower policy, the university will take reasonable steps to protect persons who file reports in good faith from retaliatory actions based on such filing.

At Kent State, reports of concerns regarding the welfare of animals used in research can be reported to the ORC in multiple ways, including:

- KSU Animal Incident Report – Report forms are pre-numbered and are posted throughout the animal facilities. Individuals can complete the form and remain anonymous or, can provide their name on the form if they would like to be contacted during the investigation or with the results of the investigation. Forms are to be filed with the ORC in Cartwright Hall.
- Online Animal Concerns Report – An [online data collection tool](#) is available 24 hours per day, 7 days per week from the Research Compliance website. Individuals can use the application and report their concern anonymously or, can provide their name if they would like to be contacted during the investigation or with the results of the investigation.
- Email, Phone, Mail, or in-person – Individuals can report concerns regarding the care and use of animals in research at Kent State to the ORC via email, phone or mail. When reporting concerns ORC staff will ask individuals if they would like to remain anonymous or provide their name to be contacted during the investigation or with the results of the investigation.



Investigations of Reports of Noncompliance or Concerns with Animal Welfare

1. Upon receipt and review of an animal incident/noncompliance report, the ORC shall consult with the IACUC chairperson and Attending Veterinarian (AV) to determine an appropriate course of action. If necessary, the institutional official (IO) and university counsel may be consulted regarding the contents of the report and the resulting actions.
2. Person(s) and/or facilities named in reports or allegations and the Principal Investigator of the study, will be promptly notified of the reported concern via an email from the ORC. A copy of this policy shall also be provided.
3. Actions or events that disregard or violate federal regulations governing the care of use of animals in research, IACUC policies, or university policies are classified as minor, serious, or continuing noncompliance. These actions are not mutually exclusive.
 - Minor: act that does not cause an animal any pain or distress, or cause an animal to experience morbidity or mortality. Minor noncompliances include administrative lapses which have no effect on the physical or psychological welfare of an animal, or actions that affect an animal or colony but cause no pain or distress.
 - Serious: significant deviation from PHS Policy or IACUC-approved protocol procedures; an action that is or may be a threat to the health and safety of animals or humans, or a situation in which animals have experienced harm or death.
 - Continuing: repeated acts of noncompliance (minor or serious) by the same individual(s), or research group.
4. In all cases, the PI has the opportunity to respond to noncompliance allegations or concerns regarding animal welfare. Unless circumstances require additional time, a written response or meeting with the investigator and lab staff is requested within 14 days of the report of noncompliance (depending on the nature of the alleged noncompliance), to facilitate review and conclusion of the matter. PIs are sent the *Notification of Report of Concern Regarding Animal Welfare* form to complete and return to the IACUC.
5. The IACUC is informed of all reports and/or concerns with animal welfare via the IACUC meeting materials. Information from the initial inquiry, summary report from the subcommittee, the PI's response (if any), and any other relevant materials (e.g., research protocol, facility records, occurrence of previous noncompliance, etc.) are distributed to all members in advance of the convened meeting.
6. The IACUC reviews the information provided and may determine that additional information is needed, or additional action(s) should be taken based upon the nature of the noncompliance, the degree to which the animals or research staff were placed at risk, occurrences of previous noncompliance, etc. Possible range of actions include, but are not limited to:
 - Recommendations for immediate corrective action



- Dismissal of allegation (i.e., unsubstantiated claims)
 - Further investigation by an IACUC subcommittee
 - Modifications to the animal use protocol
 - Education or training for PI and/or research staff
 - Monitoring of animal use activity
 - Suspension or termination of IACUC approval
 - Referral to other university process (e.g., misconduct review)
7. Investigations by an IACUC subcommittee may include interviews with or requests for written responses from witnesses of noncompliance (if applicable) and/or the PI whose personnel have been observed in noncompliance. Audits of research records may be performed.
 8. All reasonable efforts will be made to notify the Investigator(s) in writing within 5 business days of the decision of the IACUC. As applicable, notification of outcome is sent to the person(s) originating the report of noncompliance.
 9. To appeal an IACUC decision, the PI should respond in writing within 14 working days of receiving notification of an IACUC decision, or request attendance at the next IACUC meeting to discuss the issue with the committee.
 10. The ORC is responsible for preparing drafts of letters to investigators or regulatory agencies. Letters to investigators are signed by the IACUC chairperson. The AV, facility manager are copied on the correspondence. Written reports to regulatory agencies are signed by the IO and submitted by the ORC.

ANIMAL INCIDENT REPORT

Use this form to report any potential areas of concern about animal welfare.
Please return the completed form to:

Research Compliance Office
Kent State University
CARTWRIGHT HALL
Kent, Ohio 44242

YOU MAY CHOOSE TO REMAIN ANONYMOUS. TO OBTAIN INFORMATION CONCERNING
THE OUTCOME OF THIS REPORT, CALL THE RESEARCH COMPLIANCE OFFICE AT
330.672.2704 (Compliance Office) or 330.672.2263
REFER TO THE UNIQUE IDENTIFYING NUMBER LISTED ABOVE.

*Under no circumstances will reporting such instances be detrimental to an individual's standing within the University as
this action is protected under the law (9CFR, Part 2, Subpart C 2.32 (c)(4)).*

Date of incident: _____ Time of incident: _____

Animal species & identification: _____

Facility: _____ Location: _____

Discovered by: _____ (YOU MAY CHOOSE TO REMAIN ANONYMOUS)

Describe incident: (PLEASE BE SPECIFIC AND INCLUDE THE NAMES OF PERSONNEL INVOLVED)

SAMPLE
VOID

For IACUC use only: Action taken (specify): _____ _____ _____ _____ _____ _____
--

Animal Export Guidelines



1. No animals shall be shipped from any Kent State University animal facility without prior authorization of the facility manager/supervisor/director.
2. An “Animal Export Request” form must be completed and received by the animal facility manager/supervisor/director.
3. The animal facility manager/supervisor/director will request a health exam by the attending veterinarian.
4. The health report, sentinel testing reports, and a description of the facility animal husbandry practices will be sent to the receiving institution’s veterinarian and/or manager.
5. The receiving institution must approve the health status and authorize shipment, in writing, before shipment will be initiated.
6. The facility responsible for shipping costs will schedule a date for shipment and notify all parties involved. Shipment must be with an established animal shipping company, such as, World Courier, Airnet, or Validated Delivery Solutions.
7. Animals to be shipped must be tagged, “Hold for Shipment”.
8. Animal facility personnel will place the animals in suitable animal shipping crates the morning of shipment. Sufficient food and water for the duration of shipment will be placed in each crate. Crates will be labeled with all pertinent information.
9. Animal facility personnel will transport the crates to the shipping dock at the scheduled pick up time.
10. The receiving facility will be notified when animals have departed from Kent State University.

Animal Export Request



Cunningham Hall Animal Facility

Exporting Facility Information

Principal Investigator (PI) Name: [Click here to enter text.](#)

PI Phone Number: [Click here to enter text.](#)

PI Email: [Click here to enter text.](#)

Lab Contact (If other than PI): [Click here to enter text.](#)

Contact Phone Number: [Click here to enter text.](#)

Contact Email: [Click here to enter text.](#)

Desired Shipping Date: [Click here to enter text.](#)

KSU Protocol Number: [Click here to enter text.](#)

PI Responsible for Shipping Costs: ☐ Yes ☐ No

Preferred Shipping Company: [Click here to enter text.](#)

Shipping Company Account Number: [Click here to enter text.](#)

Importing Facility Information

Principal Investigator (PI) Name: [Click here to enter text.](#)

PI Phone Number: [Click here to enter text.](#)

PI Email: [Click here to enter text.](#)

Receiving Institution: [Click here to enter text.](#)

Department: [Click here to enter text.](#)

Department Contact Name: [Click here to enter text.](#)

Contact Phone Number: [Click here to enter text.](#)

Contact Email: [Click here to enter text.](#)

Attending Veterinarian Name: [Click here to enter text.](#)

Attending Veterinarian Phone Number: [Click here to enter text.](#)

Attending Veterinarian Email: [Click here to enter text.](#)

Shipping Address of Receiving Institution: [Click here to enter text.](#)

Receiving Institution Responsible for Shipping Costs: ☐ Yes ☐ No

Preferred Shipping Company: [Click here to enter text.](#)

Shipping Company Account Number: [Click here to enter text.](#)

Animal Information

Species: [Click here to enter text.](#)

Strain: [Click here to enter text.](#)

Total Number of Animals to be shipped: [Click here to enter text.](#)

Number of Males: [Click here to enter text.](#)

Number of Females: [Click here to enter text.](#)

Number of Sentinels (if requested): [Click here to enter text.](#)

Current Housing Room: [Click here to enter text.](#)

Genotype: ☐Mutant ☐KO ☐Tg

Immune System: ☐Normal/Competent ☐Deficient ☐Unknown/Undetermined

Pathogen Status: [Click here to enter text.](#)

List Any Abnormalities: [Click here to enter text.](#)

Signature: [Click here to enter text.](#)

Date: [Click here to enter text.](#)

When Animal Use Protocols May or May Not be Required**GUIDANCE****YOU MUST SUBMIT AN ANIMAL CARE AND USE PROTOCOL FORM:**

1. You plan to use live vertebrate animals for teaching, testing, or research at Kent State University (including regional campuses and centers).
2. You submit a grant application that includes the use of live vertebrate animals at Kent State University for which the funding will be administered by the University.
3. You receive or plan to receive funding administered by the University for studies of live vertebrates at another institution (whether or not the animals are owed by Kent State University, a University based investigator, or by the host institution).

No animal work can proceed until a protocol has received full Institutional Animal Care and Use Committee (IACUC) approval.

YOU **MAY NOT NEED TO SUBMIT AN ANIMAL CARE AND USE PROTOCOL FORM:**

1. You use invertebrates.
2. You are involved in a project at a PHS assured institution which involves vertebrates for which Kent State University provides no funding, no aspect of the animal research takes place at Kent State University, and the animals are not owned by the University or a University-based investigator. The IACUC may require documentation of the host approval.

YOU PLAN TO USE TISSUE ACQUIRED FROM A VERTEBRATE ANIMAL:

1. You must notify the IACUC if you are using tissue from vertebrates that have already been euthanized under approval by Kent State University or other IACUC or regulatory body. The IACUC may require the submission of supporting documentation (i.e. an IACUC approval letter) for tissue received from other institutions.

Semiannual Program Review and Facility/Laboratory Inspection

Standard Operating Procedure

In accordance with the Animal Welfare Act (9 CFR CH.1, Part 2 – Subpart C, 2.32(4c)) and Public Health Service (PHS) policy (IV.B.1-3) the Institutional Animal Care and Use Committee (IACUC) must review, at least once every six months, the institution's program for humane care and use of animals and conduct a physical inspection of all buildings, rooms, areas, enclosures, and vehicles used for the animal confinement, transport, maintenance, breeding or experiments inclusive of surgical manipulation using the Guide for the Care and Use of Laboratory Animals (Guide), PHS Policy and United States Department of Agriculture (USDA) regulations as a basis for review and evaluation.

Responsibilities:

- Office of Research Compliance
 - Schedule inspections/reviews and notify IACUC members and Principal Investigators.
 - Draft reports.
 - Provide guidance to IACUC members.
 - Report deficiencies and recommendation to PIs.
 - Submit the final report (including minority views) to the IO on behalf of the IACUC.
- IACUC
 - Conduct program review and facility inspections. No committee member who wishes to participate will be excluded.
 - Review responses/corrective action.
 - Review and comment/approve the report to the Institutional Official (IO).
- Principal Investigators:
 - Must be present during the inspection (or an experienced lab member).
 - Respond to/correct deficiencies and recommendations and report response/correction to the IACUC for follow-up if required.
- Other
 - Ad hoc consultants may be used, but cannot serve in place of an IACUC member.

Program Review Procedure:

- The Office of Research Compliance staff facilitates the review process.
- The review team consists of at least two voting IACUC members.
- The team is provided with supporting documents (i.e. OLAW Program Review Checklist, *Guide*) and results from prior inspections.
- All relevant documents are made available to the team.
- The team will review deficiencies and determine if they are major or minor along with timelines for correction and recommendations. These are recorded and included in the report to the IO.
- The IACUC is presented with the results for discussion and comment/approval.
- Upon IACUC approval, the report is distributed to the IO.
- Corrective action is taken by the appropriate personnel within the allotted timeline.

- A follow up review is scheduled as necessary.

Facility/Laboratory Inspection Procedure:

- Facility management facilitates the inspection process.
- The inspection team consists of at least two voting IACUC members.
- The team is provided with supporting documents (i.e. OLAW Inspection Checklist, *Guide*) and results from prior inspections.
- Laboratories and facilities are made available to the team.
- The team will review deficiencies and determine if they are major or minor along with timelines for correction and recommendations. These are recorded and included in the report to the IO.
- The IACUC is presented with the results for discussion and comment/approval.
- Upon approval of the IACUC, the report is distributed to the IO.
- Corrective action is taken by the appropriate personnel within the allotted timeline.
- A follow up review is scheduled as necessary.

Post Approval Monitoring

Standard Operating Procedure

Continuing IACUC oversight of animal activities is required by federal laws, regulations and policies. Post approval monitoring (PAM) is a process through which the IACUC ensures program integrity and compliance.

At Kent State University the IACUC, investigators, animal care, veterinary and compliance staff may all conduct PAM, which can also serve as an educational tool and an opportunity to refine research procedures.

Concerns related to animal welfare should be reported to the Office of Research Compliance according to the procedures described in the "Reports of Concerns and Investigations Involving Animal Care and Use" policy.

Methods of PAM include:

- Continuing protocol review
- Laboratory inspections or visits (conducted either during regular facility inspections or separately)
- Veterinary or IACUC observation of selected procedures
- Observations of animals by animal care staff, veterinarian, investigators, and/or IACUC members
- External visits and inspections
- Whistle blower/reporting of concerns procedures

Common topics:

- Review of surgical and post-operative outcomes
- Proper use and storage of drugs and chemicals
- Use of PPE and other occupational health controls
- Review of personnel training
- Review of protocol and laboratory/facility records

Communication procedures:

Components of PAM may include animal health observations and protocol compliance issues. Animal health observations made by and/or reported to the AV are reported to the PI and the animal facility manager by the AV via email along with directions for veterinary care of the affected animal(s). Protocol compliance issues are reported to the IACUC using the procedures described in the 'Reports of Concerns and Investigations Involving Animal Care and Use'

Holding Protocol

POLICY

The intent of Holding Protocol (HP) is to allow animals to be kept in the Kent or Cunningham Hall facilities for a limited time without any experimental treatments/interventions being done to them other than procedures intended to preserve the well-being of the animal. The animals may have had procedures performed on them (under approval on their original protocol) prior to transfer to this protocol.

SITUATION WHICH MAY RESULT IN THE USE OF THIS PROTOCOL MIGHT INCLUDE:

- Animals ordered without an approved protocol.
- Animals originating from expired or inactive (or terminated) protocols.
- Animals on a protocol under investigation for potential issues of noncompliance where the welfare or wellbeing of the animals is in question.
- Investigators that have separated from the University.

Requests to place or remove animals on the HP can be made by holding protocol or experimental protocol PI, the IACUC Chair, Facility Management, or the Attending Veterinarian (AV) by completing the Animal Care Holding Protocol Placement Form or the Animal Care Holding Protocol Removal Form. The placement and removal from the protocol must be made by the same person.

MANAGEMENT OF ANIMALS ON THE HP:

1. No experimental procedures are allowed to be performed on animals maintained on the HP.
2. Any use of animals on the HP will be treated as serious regulatory noncompliance.
3. Feeding, sanitation and environmental enrichment will be performed as expected for the species. Husbandry duties may be performed by the Animal Care staff, the PI or previously approved personnel depending upon the circumstances.
4. No tissues may be utilized from animals euthanized without specific IACUC approval.
5. Animals may not be euthanized for research purposes.
6. Other than animals already on the HP, no additional animals may be ordered in anticipation of IACUC approval of a new or renewal study.
7. Animal Care staff must be notified of all significant pre-existing conditions prior to transfer of animals onto the holding protocol. Examples include but are not limited to:
 1. Existing surgical implants.
 2. Zoonotic disease or other hazard.
 3. Special dietary needs.
 4. Past surgical history.
 5. Viral vectors.
 6. Poor fecundity.

Animals may remain on the HP for up to 45 days or longer as approved by the IACUC Chair after consultation with the Attending Veterinarian.

If holding protocol timelines elapses or if the renewal protocol is not approved, animals on the HP may be transferred or euthanized. *In the case of wildlife studies, it may not be appropriate to euthanize the animals. In such cases, the investigator may release the animals in accordance with any applicable guidelines and regulations.*

NEEDLE RECAPPING

POLICY

To reduce the risk of needle sticks, cuts, and punctures and to support a safe work environment, the IACUC requires that all used needles must be disposed of in an appropriate sharps container immediately after use **WITHOUT RECAPPING**.

Needles must never be recapped with one exception; needles which have NOT been in contact with an animal **and** have been charged (prefilled) for future use may be recapped by using a one-handed technique – see procedure below. Charged needles should be labeled and used the same day. Do not draw more of the preparation than is needed.

Needles must never be intentionally broken or bent prior to disposal.

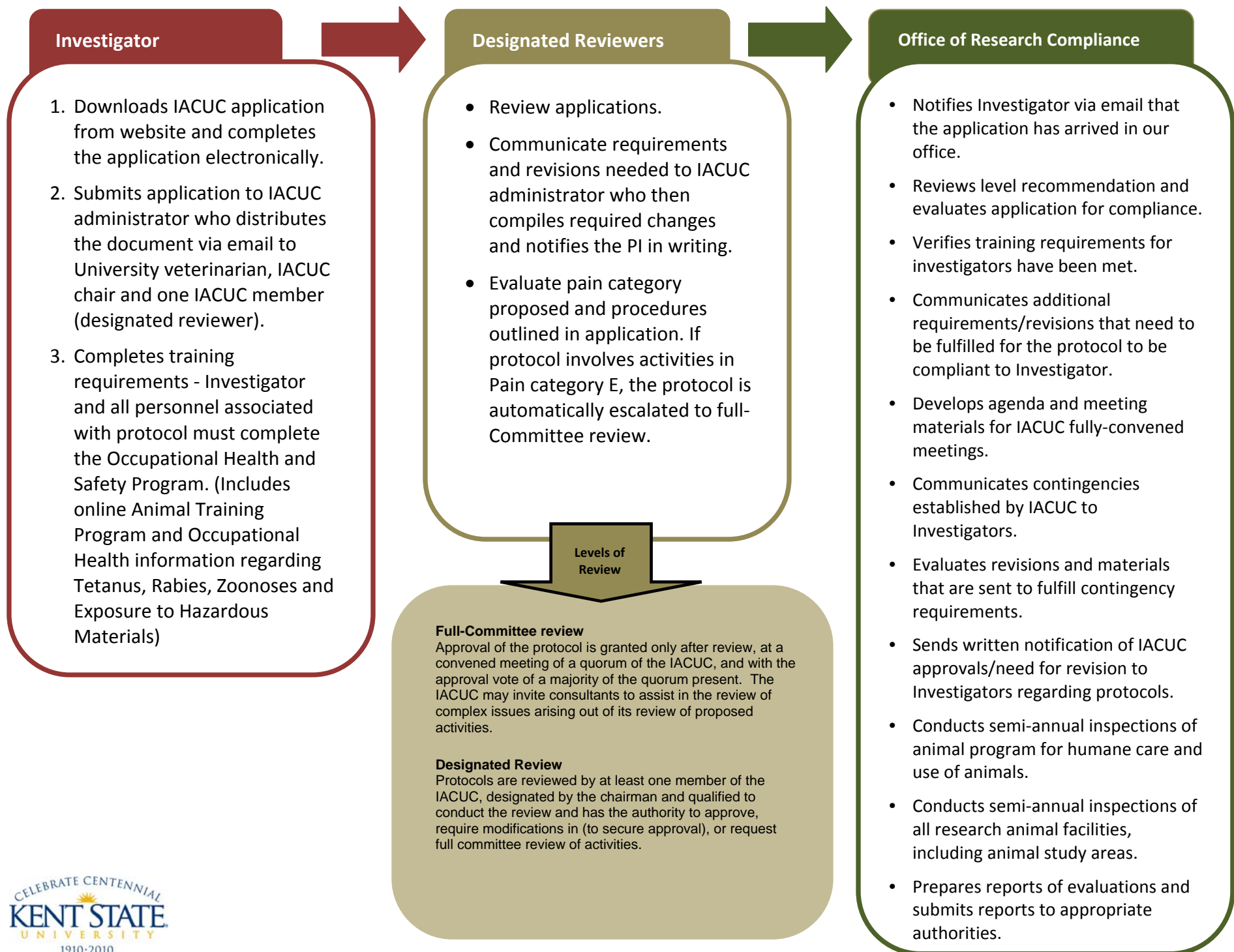
Responsibilities:

- Office of Research Compliance
 - Facilitate ongoing review of this policy
- IACUC
 - Ensure investigators are educated about this policy
 - Review the policy at appropriate intervals
 - Examine sharps containers during inspections or other lab visits
- Principal Investigators
 - Review this policy with all personnel working in their lab
 - Ensure that sharps containers are easily accessible

One handed recapping **procedure** per the Food and Drug Administration:

1. Place the cap on a flat surface like a table or counter with something firm to “push” the needle cap against.
2. Holding the syringe with the needle attached in one hand, slip the needle into the cap without using the other hand.
3. Push the cap needle against a firm object to “seat” the cap onto the needle firmly using only one hand.

An Overview of the Institutional Animal Care and Use Committee (IACUC) Process at Kent State University



SOCIAL HOUSING and ENVIRONMENTAL ENRICHMENT**POLICY**

To support an environment that promotes positive animal welfare and that meets regulatory requirements (*Guide 8th Ed.*), the IACUC considers social housing (two or more animals in a cage) the default. Any animals housed individually must be provided an enriched housing environment. Exceptions to this must be approved by the IACUC with scientific justification or as deemed appropriate for the provision of veterinary care or other welfare related concerns, including post-operative recovery. The IACUC understands there may be other extenuating circumstance that require or result in occasional single housing to ensure the health and survival of the animals; this *may* include the receiving of animals shipped single housed or the separation of non-socially compatible animals. Animals should be provided enrichment and facility staff must be notified.

Exceptions to social housing and enrichment standards should be limited to the minimum necessary time period. Enrichment must be provided to singly housed animals.

Responsibilities:

- Principal Investigators
 - Seek an exception through the protocol review process with scientific justification
 - In collaboration with facility personnel, ensure all animals are socially housed by default and provided with sanitary enrichment
 - Maintain records in a manner that allows the veterinary, animal care staff, and the IACUC that an exception has been approved (for example, door signs may indicate the exception)
- IACUC
 - Ensure investigators are educated about this policy
 - Review the policy at appropriate intervals
 - Review, approve, disapprove or require modifications to secure approval of any exceptions of this policy on a protocol-by-protocol basis
 - Report exceptions to these standards to the IO as part of the semi-annual program review and inspection process
 - Investigate concerns related to these standards
- Office of Research Compliance
 - Facilitate the review of exemptions
 - Maintain a spreadsheet listing all exceptions
 - Facilitate ongoing review of this policy
 - Report deviations from the policy to regulatory agencies and accrediting bodies

Examples of species commonly housed at Kent State University:

- Mice

- Should be housed with socially compatible groups. Consult appropriate literature for additional information.
- Individually housed animals must be provided with appropriate enrichment, or scientifically justify why this is not allowed.
 - This may include Nestlets, Nylabones, paper towels, wood blocks, plastic/paper huts (when permissible) or other suitable products as approved by the IACUC for mice. Mice may also be given sunflower seeds or seed mix.
- Rats
 - Should be housed with socially compatible groups. Consult appropriate literature for additional information.
 - Individually housed animals must be provided with appropriate enrichment, or scientifically justify why this is not allowed.
 - This may include wood blocks, Nylabones, Nestlets, paper towels, cardboard/plastic tubes, tubing, or food enrichments such as nuts or cereal or other suitable products approved by the IACUC. Rats may also be given sunflower seeds or seed mix.
- Avian Species
 - Must be housed with socially compatible groups
 - Other social species will be housed with socially compatible groups. Consult appropriate literature for additional information.
 - Must be provided with appropriate enrichment
 - This may include cuttle bones, gravel, grit, perches, or fresh fruit and vegetables

Sanitation and disposal

- Discard disposable items at suitable intervals (for example, nestlets for mice typically last two weeks)
- Sanitizable items should be sanitized at appropriate intervals (for example, items can be washed with detergents and/or hot water and, where appropriate chemical agents – see *Guide* p. 71)

SMALL ANIMAL (e.g. RODENTS AND BIRDS) SURVIVAL SURGERY

STANDARD OPERATING PROCEDURE

In order to provide small animals with the highest care during survival surgical procedures, an aseptic technique is required.

Preparation of the Procedural Site

- The procedural site must be dedicated to that purpose while surgery is conducted. This area should be separated from high-traffic areas and free of unrelated equipment and supplies. If possible, the procedural site should be subdivided into separate areas for animal preparation, surgery, and recovery.
- The surgery table and associated equipment (e.g., stereotaxic apparatus) must be sanitized prior to use. Suitable products for disinfecting the surgery area include a disinfecting soap and water rinse, 70% alcohol, and quaternary ammonium based disinfectants.
- Covering of the surgical surface with clean paper (e.g., plastic-backed lab bench paper) or cloth will help prevent hypothermia and absorb fluids.

Preparation of the Surgical Instruments and Supplies

- Surgical instruments and implantable materials must be sterilized by an approved method. Sterilization may be achieved via autoclave or by other means as approved by the IACUC. Autoclaving generally is the preferred method for sterilization because of its convenience, and efficacy. Depending upon the nature of the surgical procedure, the degree of instrument contamination during the surgery, and the type of animal, a sterile set of instruments may be used for up to 2-5 small animals during the same surgery session. Instruments must be decontaminated during the procedure and between animals using a point heat source, such as a glass bead sterilizer. Exercise care to allow the instrument to cool down before use.
- Instruments and other autoclavable supplies such as gauze pads and drape material can be easily placed within disposable sterilization pouches designed for that purpose or double-wrapped in reusable cloth towels/drapes. Autoclave confirmation tape or color-change indicators should be used in/on each pack that is autoclaved and the date on which the items are autoclaved should be written on the pack. Autoclaved instruments are considered sterile for variable lengths of time depending on the manner in which they are wrapped. Double cloth wrapped instruments stored in an enclosed cabinet or container and protected from moisture are recognized as sterile for up to 6 months unless the integrity of the wrapping is compromised. Scalpel blades should be purchased sterile and not autoclaved as they are dulled by autoclaving.
- The same methods used to sterilize instruments may be applicable to implantable materials. Some materials may be commercially available as a sterile product (e.g. polyethylene tubing).

- Surgical instruments should be cleaned with an instrument cleaner or soap and water, rinsed, and dried after each surgery session. A soft toothbrush or test tube brush is often useful for thorough cleaning of delicate instruments. Instruments should be stored such that the cutting edges, tips, and points are protected from damage. Instruments should be sharpened periodically as needed.

Preparation of the Animal

- Food and water are not usually withheld from rodents unless there is concern about ingesta within the gastrointestinal tract as may occur for abdominal surgery. If this is the case, it needs to be justified in the approved protocol. Food and water withholding is not recommended in rodents for more than 12 hours.
- Preparation of the animal is usually best done in an area close to, but separate from, the surgery area.
- Plucking or shaving with electric clippers are preferred techniques for removal of fur/hair. Depilatories and razor shaving should be used carefully due to the potential for dermal irritation. Loose hair can be removed with a vacuum, tape, or wet gauze.
- The depilated area should extend well beyond the surgical margins so as to facilitate the maintenance of aseptic technique during surgery, but not so far as to contribute to hypothermia.
- Gauze sponges and cotton-tipped applicators are convenient means to wash, rinse, and disinfect the surgical site. The use of cotton tipped applicators are preferred because they help to minimize loss of body heat that may be associated with excessively moistening the skin surface.
- The surgery site must be aseptically prepped including removal of hair and disinfection by an approved method. For rats and guinea pigs washing with iodine or a chlorhexidine-based surgical soap (e.g. Betadine scrub or Nolvasan scrub) followed by disinfecting with 70 percent alcohol; alternating with an iodine solution is acceptable. For mice, 3 applications of 70 percent alcohol alternating with 3 applications of iodine solution can be used.
 - A new gauze sponge or cotton-tipped applicator should be used for each application.

Surgical Technique

- Sterile gloves, a surgical mask, cap, and a clean outer garment (e.g., lab coat or scrub top – not street clothes) are required. Exam gloves may be used provided that they are disinfected with a product such as Spor-Klenz (or other IACUC approved disinfectant) and allowed to dry for a minimum of one minute before use.
- The surgery should be conducted so as to minimize trauma to the tissues and preserve the sterility of the instruments and the surgical field. It should be completed as quickly as possible without compromising technique; tissues should be handled delicately and depending on the nature of the surgery, kept moist with warm, sterile saline. Sutures and staples should not be placed too tightly. A subcuticular skin suture pattern will often preclude the chewing and removal of sutures by the animal.

- Whenever possible, the surgery site should be draped with sterile cloth, paper, surgical gauze, or clear adhesive vinyl to minimize the risk of contamination to the surgery site. Care should be taken to avoid placing a drape such that the animal cannot be monitored. Drapes can have the added benefit of keeping the animal warm.
- Animals should be kept warm using an external heat source, particularly for procedures of any significant length (i.e., longer than 30 minutes). An electric or water circulating (preferred) heating pad, an overhead heat source such as a lamp or hand warmers can be used. Great care must be taken to prevent overheating or burning the animal. In all cases the external heat source should be separated from the animal by a towel or other protective barrier.
- Anesthetic agents must be suitably scavenged to prevent inadvertent exposure to humans or animals. A F/Air canister or fume hood can be used. If F/Air canisters are used, they are weighed before and after each use. After an increase of 50 grams over the initial weight the canisters are disposed of properly. For prolonged procedures, particularly those accompanied by blood loss, warmed fluid therapy should be administered. The recommended amount is equal to 1-2 cc per 100 g body weight per hour of anesthesia plus any blood loss. Because of the small size of the patients covered by this policy, the intraperitoneal or subcutaneous routes are usually used.
- During the surgery the animal's respiration, tissue color and response to aversive stimuli should be monitored so that corrective action can be taken promptly if necessary.

Recovery from Surgery

- Depending upon the nature and duration of the surgery, it may be necessary to provide the post-operative patient with an external heat source during the recovery period. As described above, steps should be taken to protect the animal from the heat source. At the very least, animals should be placed on absorbent material or substrate or provided with other external insulating material (e.g. a towel). Animals recovering from anesthesia or surgery should not be recovered in a wire bottom cage.
- During the recovery period, the animal's clinical condition should be monitored. Specific observations should include the body temperature, respiratory pattern, condition of the surgical wound, and the strength and rate of heartbeat.
- Rodents can often be stimulated to breathe in the case of apnea using gentle chest compression or inflating the lungs with a rubber bulb (from a pipette) applied to their nostrils. Supplemental oxygen may be beneficial.
- Animals must be monitored until they have recovered satisfactorily from anesthesia, i.e., normal respiration, sternal posture and moving about.
- The date and a brief description of the surgical procedure, including any drugs administered and the anesthetic agent(s) used, and analgesics used, must be noted on the animal's cage card.
- Mice and rats cannot remain in investigator laboratories or other unapproved housing areas for longer than twenty-four hours without IACUC approval. USDA-covered species cannot remain in unapproved housing areas for > 12 hours.

Post-Procedural Monitoring

- Animal must be monitored post-surgically as often as necessary to assure their well-being, depending upon the nature of the procedure and the condition of the animal. Post-surgical monitoring may range from once daily for one or two days to multiple times per day for extended periods.
- Any abnormal findings must be recorded on the cage card and the veterinarian should be contacted directly or through the facility manager.
- Conditions of observation are reviewed by the IACUC at the time of protocol review. In some cases, such as when the same procedure is conducted on many animals, alternative methods of record keeping (other than on a cage card) can be used but should be kept near the animals for review. Please contact your facility manager to discuss alternative means of record keeping.

Responsibilities:

- Office of Research Compliance
 - Facilitate ongoing review of this procedure
 - Report deviations from the procedure to regulatory agencies and accrediting bodies
- IACUC
 - Ensure investigators are educated about this procedure
 - Review this procedure at appropriate intervals
 - Investigate concerns related to these standards
- Principal Investigators
 - Ensure all personnel involved in surgical procedures are trained on this procedure
 - Maintain surgical records and permit the IACUC access to surgical records

Kent State University Animal Tissue Transfer/Usage

Please provide the following information

KSU Principal Investigator:

Department:

Campus Phone and Email:

Protocol Title/Number:

Tissue Source

Name:

Phone number and Email:

Institution:

Protocol number/ title under which tissue was collected:

OLAW Welfare Assurance Number:

Tissue Requested

Species:

Tissue Type:

Quantity:

Frequency of Transfer:

Method of Transfer:

Does this project require euthanizing animals for the purpose of obtaining or using their tissues or other materials, or involve project-specific antemortem manipulations of animals prior to euthanizing them?

Yes ☐ No ☐

The use of dead animals or parts of animals is not covered by the PHS Policy unless the activity involves (1) euthanizing animals for the purpose of obtaining or using their tissues or other materials, or (2) project-specific antemortem manipulation of animals prior to euthanizing them. If either circumstance is applicable to the acquisition of dead animals, body parts or tissues, prior IACUC protocol review and approval are required.

Hazard Potential

Has the tissue been screened for human/animal pathogens? Yes ☐ No ☐

Will tissue be treated (preserved, digested etc.) prior to transfer to KSU? Yes ☐ No ☐

- If Yes, provide description of how tissue is treated:

Will tissue be transferred into live animals? Yes ☐ No ☐

- If Yes, provide protocol information describing procedure:

Was the animal intentionally or otherwise suspected to be infected? Yes ☐ No ☐

- If Yes, provide information on the organism/disease:

Are there any additional hazards associated with this tissue? Yes ☐ No ☐

- If Yes, provide description of hazard:

Tissue Use

Briefly describe how tissue will be used:

Describe method of tissue disposal:

Personnel Training

Describe personnel training for procedures with this tissue:

Permits: It is the responsibility of the PI/Research Leader to have all necessary permits from regulatory agencies such as CDC, FDA, Fish and Wildlife etc. in place prior to receipt of tissue. Applicants are encouraged to contact the ORC for guidance.

Shipping and Receiving: Must be conducted in accordance with federal shipping and importation guidelines. The PI is responsible for being in compliance with all regulations regarding shipping tissues that may have been exposed to animal diseases or present a zoonotic risk to humans. The Kent State [Office of Laboratory Safety](#) may be able to provide guidance on Standard Operating Procedures (SOPs) for sample handling and transport.

Location/Safety Measures: Indicate the building and room number where the tissue will be kept. Describe safety and containment measures taken to prevent spread of potentially infectious disease contained in the tissues. Describe security measures taken to prevent theft/loss of tissue. Facility may be inspected prior to tissue delivery.

Signatures: PI must initial/sign the following, verifying that each statement is true:

This description is accurate and complete. All personnel are adequately trained to perform these procedures and are enrolled in the occupational health program. Safety practices will be adhered to. All vertebrate animal tissues will be acquired through lawful means, judiciously used and disposed of appropriately. I have read and understand the guidelines associated with this application. (Initial)

Tissue proposed for use is not from an endangered species (Initial)

Tissue shipment does not violate the Convention of International Trade of Endangered Species (CITES). (Initial)

Tissue proposed for use and its shipment does not violate the Migratory Bird Act. (Initial)

Signature of PI:

Date:

KSU email address:

Signature Attending Veterinarian or IACUC representative: _____

Date: _____

(This signature will be facilitated by the ORC)

Obtaining the Approval of Three Year Renewals and Annual Reviews

STANDARD OPERATING PROCEDURE

According to the Public Health Service (PHS) guidelines, protocols can only be approved for a three (3) year period, after which the investigator is required to submit a new protocol in order to continue the project. In order to comply with these guidelines and the requirements of the Animal Welfare Regulations (AWR), the IACUC will review all protocols annually through the use of an annual review form and require a new protocol submission every three years (IACUC Policy and Procedure Manual 2-01).

WHEN AN ANNUAL REVIEW OR THREE YEAR RENEWAL OF AN ONGOING PROJECT IS NOT APPROVED IN A TIMELY MANNER:

The Office of Research Compliance makes every effort to provide investigators timely reminders of project renewal dates. However, it is the responsibility of Principal Investigator (PI) to be aware of project expiration dates and to submit the required materials accordingly. In instances where the appropriate approvals are not obtained in a timely manner the Office of Research Compliance will initiate the following steps:

1. An email memo will be sent to Facility Management, the Attending Veterinarian, the IACUC Chair, and the PI regarding the project's expired approval status.
2. Animals will be placed on the Holding Protocol according to the procedures outlined in the Holding Protocol Policy.
3. Animals are held on the Holding Protocol until the IACUC is able to convene and review project. The PI may be invited to attend the meeting.
4. The Office of Research Compliance or the IACUC Chair communicates the IACUC's decision to Facility Management, the Attending Veterinarian, the IACUC Chair, the PI, and the Department Chair.

SANITIZING CAGING AND ACCESSORIES BY HAND

STANDARD OPERATING PROCEDURE

In some instances it may be necessary to sanitize cages and accessories by hand. For example, in emergency situations, or when an IACUC approved protocol involves alternative or specialized housing. *Please refer to the emergency preparedness manual for situations where power failures or other emergencies may be in effect.* Housing, water bottles, bottle stoppers/sipper tubes, feeders, enrichment items and other small pieces of equipment should be washed with detergents, hot water (note: some detergents may require water to achieve a certain temperature), and where appropriate, chemical agents to destroy microorganisms.

Equipment Needed:

- Quatricide PV (Pharmalac #68020) or equivalent or better
- Cloths, sponges, brushes
- Bucket
- Deep sink
- House water supply
- Personnel Protective Equipment (plastic aprons, rubber boots, cap, mask, rubber gloves, goggles)

Method:

1. Dilute Quatricide (2 ounces per gallon) or equivalent or better solution in bucket with house hot water
2. Thoroughly wash all interior/exterior surfaces of soiled caging, accessories, bottles, etc. with solution
3. Thoroughly rinse caging until all evidence of residual solution is gone
4. Allow caging to drain and air dry before filling/stacking for reuse
5. If the manufacturer provides written guidance, their methods should be followed

Additional Disinfection for Water Bottle Stoppers and Sipper Tubes:

Disinfecting water bottle stoppers/sipper tubes presents a unique challenge since it is difficult to determine if all interior surfaces have been properly decontaminated. Therefore, in addition to washing and rinsing as described above, these items require additional attention to assure disinfection.

1. Place bottle stoppers/sipper tubes in accessory basket
2. Immerse basket of bottle stoppers into a 10% bleach solution; soak for 15 minutes
3. Manually agitate the basket of stoppers back and forth and up and down carefully through the bleach solution several times
4. Thoroughly rinse all items and allow to drain before re-circulating for use
5. If the manufacturer provides written guidance their methods should be followed

Assessing the effectiveness of disinfection and sanitization:

The effectiveness of manual cage washing should be monitored more frequently than when using conventional methods of cage cleaning (i.e., cage and rack washers). Weekly testing of clean cages and accessories should, therefore, be taken during those times when manual cage washing is being performed.

Method for assessing the effectiveness of disinfection and sanitization:

1. Conduct adenosine triphosphate (ATP) testing and record results (see facility management for details).
2. Microbiological cultures may be conducted as needed.

Veterinary Verification and Consultation for Significant Changes and other Minor Changes to an Approved Project

POLICY

To reduce paperwork, minimize delays, and to be consistent with NIH guidance on Veterinary Verification and Consultation (VVC) and minor changes to an already approved project, the IACUC has developed this policy. This policy does not apply to USDA covered species.

The approval of these changes can be sent immediately upon notice from both the Attending Veterinarian and the IACUC Chair or the Office of Research Compliance (as defined below) and are not subject to a hold period. Any reviewer can request a modification to secure approval, request the submission of a full amendment form, or request full board review of a request.

Responsibilities:

- Office of Research Compliance
 - Facilitate the review of minor changes
 - Maintain record of changes and notify the IACUC in the "Notification Section" on the agenda
 - Facilitate ongoing review of this policy
 - Report deviations from the policy to regulatory agencies and accrediting bodies
 - Approve the following changes:
 - Correction of typographical errors; correction of grammar; and contact information updates
 - Changes in personnel other than the Principal Investigator. Changes in personnel must be made using the Addition of Personnel form.
- IACUC
 - Ensure investigators are educated about this policy
 - Review the policy at appropriate intervals
 - Investigate concerns related to this policy
- Principal Investigators
 - Submit supporting documents
 - Maintain records related to proposed changes
- Attending Veterinarian and IACUC Chair
 - Changes that can be approved with the approval of both the IACUC Chair and Attending Veterinarian:
 - Total increase in animal number for animals not regulated by USDA that does not exceed 10% of the number already approved by the IACUC. (*This is not intended for large increase in animals and prior authorization from the facility manager/director should be obtained to ensure the additional animals can be accommodated*)

- Changes in stock, strain, or genetic modification, unless the new stock, strain, or modification results in abnormalities that require special support
- Changes to house or use animals in a location that is currently used for the same purpose and is part of the animal program overseen by the IACUC
- Changes that would not result in greater discomfort or invasiveness to the animal, in general, this includes changes as follows (*Anesthesia, analgesia, sedation, or experimental substances, Euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals, duration, frequency, type, or number of procedures performed on an animal*)*

If a Principal Investigator is concurrently submitting changes that can be reviewed by the ORC and the Attending Veterinarian and IACUC Chair, all changes must be approved by the Attending Veterinarian and the IACUC Chair.

*The Attending Veterinarian reserves the authority to independently review and approve these changes, per NIH policy, should it be necessary.

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-063.html>

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-126.html>

OCCUPATIONAL HEALTH PROGRAM FOR PERSONNEL INVOLVED IN ANIMAL CARE AND USE

1. Background

Kent State's Animal Welfare Assurance and [Public health policy](#) requires a health program for personnel who work in laboratory animal facilities or have frequent contact with animals.

2. Overview and Purpose

The purpose of the Occupational Health Program for Personnel Involved in Animal Care and Use (OHPA) is to provide a mechanism whereby Kent State University can fulfill and manage its institutional responsibility to provide a safe workplace for KSU personnel involved in the direct care and use of animals used for research, teaching, and/or testing.

3. Definitions

- 3.1. Direct contact means that you handle animals, perform procedures on animals, or handle their (fixed or unfixed) tissue, body fluids or waste. Examples of persons with direct contact include Principal Investigators (PIs), laboratory staff, students performing animal research, and animal care personnel.
- 3.2. Indirect contact means that you do not touch animals or animal tissue and do not handle animal waste. Examples of persons with indirect contact may include facilities personnel, police, security, contractors and administrators.

4. Applicability

- 4.1. All students, faculty and staff that will be working directly with animals or animal tissues under the auspices of Kent State must enroll in the OHPA and complete the preplacement screening evaluation.
- 4.2. Personnel having only indirect contact with research animals and that do not enter the vivaria on a regular basis, or that have infrequent exposure to research animals are not required, but encouraged to participate in the OHPA.
- 4.3. Personnel concerned with exposure to laboratory animals who are not required to obtain a health assessment and medical clearance can voluntarily receive a health assessment per the program.
- 4.4. The IACUC may withhold approval for working on a protocol or in an animal facility until personnel have enrolled in the OHPA and completed applicable assessments and/or training.

5. Components

5.1. The components of the OHPA include:

- | | |
|-------------------------------------|-------------------------------------|
| • Preplacement screening evaluation | • Occupational health care services |
| • Administrative procedures | • Personal protective equipment |
| • Facility design and operation | • Equipment performance |
| • Risk assessment | • Information management |
| • Exposure control | • Emergency procedures |
| • Education and training | • Program evaluation |

6. Responsibilities

- 6.1. The IACUC is responsible for applying and implementing policies, procedures and programs in accordance with the standards published in the Guide for the Care and Use of Laboratory Animals (8th Edition), PHS Policy, the regulations as defined in the Animal Welfare Act, and Kent State University policies.
- 6.2. The Division of Research and Sponsored Programs shall bear the cost of an initial health risk assessment (if performed by UHS). Individuals are responsible for any additional costs (i.e., medical follow-up, Tetanus immunization, Rabies vaccination, etc.).
- 6.3. Office of Research Compliance (ORC) is responsible for monitoring compliance and overall coordination of the OHPA in relation to IACUC protocols.
- 6.4. Environmental Health and Safety is responsible for developing and overseeing the implementation of comprehensive safety programs to facilitate the safe use of biological, chemical and radiological materials in laboratories.
- 6.5. PIs/Instructors and/or Facility Supervisors/Managers are responsible for insuring that all personnel under their supervision are enrolled in the OHPA, ensures are trained, and are following safe practices and procedures in the animal laboratories/workspaces.
- 6.6. University Health Services (UHS) is the occupational health provider for the OHPA and is responsible for assessing animal exposure and medical history forms to determine whether the employee or affiliate can assume the duties of the animal care and use position.
- 6.7. The Attending Veterinarian (AV) is responsible for advising the IACUC, Environmental Health and Safety and the ORC regarding animal zoonoses/hazards/risks.
- 6.8. Participants are responsible for ensuring their own understanding of job responsibilities, safety procedures, research procedures, risks involved with animal care and use, and costs associated with required immunizations.

7. Program Enrollment and Participation

- 7.1. Prior to gaining unlimited access to the animal laboratories, all personnel having direct contact with animals, animal waste, and/or unfixed animal tissues must:
 - 7.1.1. Complete all OHPA requirements, including:
 - 7.1.1.1. CITI online training including species specific modules and other modules as deemed necessary by PI/Supervisor or IACUC
 - 7.1.1.2. Online occupational health preplacement screening evaluation
 - 7.1.1.3. Basic Laboratory Safety Course and other courses as deemed necessary by Environmental Health and Safety
 - 7.1.1.4. General animal facility training/orientation
 - 7.1.1.5. Laboratory/Protocol specific procedures training or other training as deemed necessary by PI/Supervisor or IACUC

8. Ongoing assessment and surveillance

- 8.1. Upon enrollment, personnel are required to complete the online OHPA preplacement screening evaluation at least every year, upon a change in work or health status, or upon recommendation from UHS occupational health practitioner, university Environmental Health and Safety personnel, or other medical professional.

Resources

[Occupational Health and Safety in the Care and Use of Research Animals](#)

[OSHA Laboratory Safety Guidance](#)

Procedures

Enrollment and participation in the OHPA is accomplished by completing the preplacement screening evaluation and resulting requirements, if any.

Kent State University
Visitor Policy for Animal Care Facilities

A. To minimize disturbances to animals being cared for in the animal care facilities of the university and avoid distractions to researchers conducting experiments or teaching students to conduct experiments, tours of these facilities will be granted only on a limited basis. Requests for tours must be made to the Division of Research and Graduate Studies and will be granted only to persons who show valid reasons for such a tour. Casual visitors are discouraged from visiting the facility. The facility director for Kent State University's animal care facilities will accompany all visitors. Because of the nature of the research work underway, the University always reserves the right to restrict access to certain areas.

B. Procedure to secure approval to tour facilities

1. Application forms for facility tour requests are available in the Office of Research and Graduate Studies.
2. The request will be considered and approved by the Vice President of Research and Graduate Studies or in his absence, IACUC Chair or IACUC Administrator.
3. Approval or denial of the request will be sent to the requesting party within approximately two weeks.

C. General conditions for approval

1. To avoid disruption of experiments, disturbance of animals and possible hazard to visitors, no approval will be given to directly observe data collection.
2. Tours will be for a limited number of persons at a time.
3. Recordings, filming, taping, photographing or related activities are prohibited, except as specifically approved.
4. Lab coats must be worn by all visitors and persons escorting the visitors.
5. If a visitor has a cold or communicable disease at the time of the visit, the visit must be canceled.
6. Smoking, drinking and eating in the animal facilities are not permitted.
7. Feeding or touching the animals in not permitted.

D. Procedures for tours

1. Arrangements for the date and time of tours will be made by the facility director based on research and class schedules.
2. A copy of the approved request form will be sent to the person requesting a visit. This form must be shown to the facility director at the time of the visit. There will be no admittance to the facility without this form. (Identification may be requested).
3. The visitor will meet at the appointed time in the facility director's office. The facility director will accompany the visitor.
4. Questions on animal care are encouraged and will be answered by the facility director or designee.

Information about the University's policy and procedures regarding animals used in research and teaching may be requested from the Division of Research and Graduate Studies (330)672-2851.

APPLICATION TO TOUR
KENT STATE UNIVERSITY'S ANIMAL CARE FACILITIES

Note: A separate request is needed for each person or group.

NAME:

TELEPHONE:

ADDRESS AND ZIP CODE:

ORGANIZATION OR SCHOOL AFFILIATION:

REASON FOR TOUR: (Add additional pages if necessary)

DO YOU HAVE ANY ANIMAL ALLERGIES?

☐ YES

☐ NO

I verify that the above information is true:

Signature of requestor

Date

Reference Source: Signature of Instructor or Supervisory Person of Requestor

Signature of Supervisory Person of Requestor

Date

Name of Supervisory Person of Requestor

Title

☐

REQUEST APPROVED

☐

REQUEST DENIED

Upon approval, tours will be scheduled with the Facility
Director based on Department schedules
REASON FOR DENIAL:

Vice President, Research and Graduate Studies

Date

Facility Director

Date

Department Chair

Date

Drugs and Chemicals Used in Laboratory Animals

Policy

This policy concerns the use of drugs and other chemicals that are to be administered to live laboratory animals.

This information supplements the policies and procedures (including the University and Laboratory chemical hygiene plans and Standard Operating Procedure forms) maintained by the [Compliance and Risk Management unit](#).

Part 1, GENERAL INFORMATION:

Cocktails/Mixtures:

1. Only the minimum amount should be mixed (i.e., prepare only enough of the mixture that may be utilized in two weeks).
2. Containers must be clearly labeled and include the following:
 - a) Cocktail name, including its components.
 - b) The date the solution was made on/prepared.
 - c) Expiration date should be described as a specific date, usually within 2-4 weeks of the mixture date or a date based on testing of efficacy or purity.
 1. The mixture expiration date must be before the earliest expiration date of any of the mixture components.
 2. Preparation and expiration dates must be in mm/dd/yy format.

Expired Drugs:

1. Expired drugs must be clearly labeled as “not for survival use” and segregated from in-date drugs. For example, in-date and expired drugs may share a common safe or cabinet, but expired drugs must be stored in a box labeled “not for survival use”.
2. Anesthetics, analgesia and euthanasia agents must never be used after their expiration date and must be disposed of upon expiration.
3. If expired drugs do not serve a purpose for currently approved projects or there are no plans to submit a supporting project, they should be disposed of [using proper disposal techniques](#).

Controlled Substances:

1. All controlled substances must be used and maintained according to the Controlled Substances Act (<http://www.deadiversion.usdoj.gov/21cfr/21usc/812.htm>).
2. Storage procedures for controlled substances must be in accordance with the regulations at http://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_72.htm.

Part 2, NON-PHARMECEUTICAL GRADE DRUGS:

Pharmaceutical-grade compounds are to be used whenever they are available, even in acute procedures. The use of non-pharmaceutical grade compounds in laboratory animals under certain circumstances may be a necessary and acceptable component of biomedical research.

In the event that a non-pharmaceutical grade compound has to be used due to (1) scientific necessity and/or (2) non-availability of a veterinary or human pharmaceutical grade compound, specific review and approval by the IACUC is required. Cost savings alone is not an adequate justification for using non-pharmaceutical grade compounds.

In addition to the justification of the use of the compound, the method of preparation of the drug and storage conditions must be described in the IACUC protocol. In particular, a detailed description of the methods used to ensure sterility of the drug must be included (e.g., sterile 0.22 micron filter, sterile diluents, storage in sterile vials with rubber septum to maintain sterility).

Responsibilities:

- Office of Research Compliance
 - Facilitate ongoing review of this policy
 - Report deviations from the policy to regulatory agencies and accrediting bodies
- IACUC
 - Ensure investigators are educated about this policy
 - Review the policy at appropriate intervals
 - Investigate concerns related to this policy
 - Review the use of non-pharmaceutical grade substances via protocol review.
- Principal Investigators
 - Justify the use of non-pharmaceutical grade substances via IACUC review.
 - Maintain records related to proposed changes

Typical justifications for the use of non-pharmaceutical grade substance:

Investigators must justify the use of non-pharmaceutical grade products and assure, to the best of their knowledge and consistent with study design, that the product is safe and is prepared in a biologically compatible manner. In cases where the effects of a non-pharmaceutical grade product or investigational drug are unknown, the IACUC may require additional monitoring of the animals to assess the impact of the product on animal welfare.

Adequate justifications for using a non-pharmaceutical grade product include:

- The unavailability of a pharmaceutical grade formulation
- Unsuitable concentration
- Formulation or vehicle of a pharmaceutical grade product
- Conduct of a study to investigate the effects of a particular compound;

- or other scientific reason.

References:

A list of pharmaceutical grade drugs and biologics is available from the Food and Drug Administration (FDA) (see <https://www.accessdata.fda.gov/scripts/cder/daf/>):

- Orange Book is the reference for the FDA approved human drugs
 - (<https://www.accessdata.fda.gov/scripts/cder/ob/>)
- Green Book lists the FDA approved veterinary drugs
 - (<https://www.fda.gov/animalveterinary/products/approvedanimaldrugproducts/>)

OLAW (Section F.4): <https://grants.nih.gov/grants/olaw/faqs.htm>

USDA (page 8):

https://www.aphis.usda.gov/animal_welfare/downloads/Animal%20Care%20Policy%20Manual.pdf

Transporting Animals

GUIDANCE

The IACUC recognizes that there may be limited instances when an animal must be transported to a satellite location that is not immediately in the animal's home building. This guidance document provides the IACUC's recommendations for developing transport plans. Animal transport and transport procedures must be approved by the IACUC and included as part of an approved *Request to Use Animals* or amendment. No animal work may occur in a satellite lab until the IACUC has inspected and approved the space, and, if necessary, on a continuing semi-annual basis.

Animals and animal caging must be transported in a contained manner to minimize animal distress, minimize risk of escape, and to protect personnel along the transport route from potential exposure to animal allergens. Additionally, it is essential to transport animals in a manner that does not expose the colony to pathogens or other contaminants.

General guidelines for transporting live animals between buildings/labs:

- It is essential to meet with your Facility Manager to discuss transport schedules and methods for limiting the introduction of pathogens or other contaminants to the vivarium.
- Water bottles must be removed prior to transport to guard against flooding.
- Cages must be tightly sealed by putting tape from bottom to the lid and enclosed in a transport container, to limit the possibility of escape. The transport container should be opaque and sanitizable.
- A lab cart should be used.
- Consideration must be given to the route and time of day the animals will be moved. Busy times and routes should be avoided.
- Transport must be done in a timely manner and animals should not remain in transport containers for more than 20 minutes.
- Transport should be avoided on days that are excessively hot or cold. Hand warmers can be placed in the transport container (not the cage) to keep animals warm.
- When possible, use disposable caging and accessories.

Return transport to the building and vivarium:

- Live animals:
 - Caging and accessories should be sanitized by chemical disinfectant if possible. Care should be given to not expose animals to chemical cleaners.
 - Animals typically need to be held in quarantine upon return. Please be advised that limited space is available in quarantine. The ability to perform experimental procedures in quarantine is limited and must be approved by the IACUC.
- Tissue and/or accessories only:
 - Tissue and accessories should be separately bagged prior to leaving the satellite location.
 - Tissue should be returned to the vivarium only if it is absolutely necessary.
 - Accessories and caging must be sanitized with chemical disinfectant prior to re-entry and immediately placed in the "dirty" cage wash using the dirty corridor.

Use of anesthetic gases in laboratory animal research

Description

This standard operating procedure (SOP) outlines the handling and use of anesthetic gases in animal research, including: isoflurane, halothane, and enflurane. If your protocol involves use of anesthetic gases in animal research, you must review this document and supply the information required in order to make it specific to your laboratory. In accordance with this document, laboratories must use appropriate controls and personal protective equipment when handling animal anesthetic gases.

Procedure Location

The use of animal anesthetic gases must be performed in an area with good ventilation and controls to capture and exhaust waste anesthetic gases.

Potential Hazards

Anesthetic gas and vapor that leaks during medical or research procedures are considered waste anesthetic gases (WAG). University faculty, staff and students should be aware of the potential risks of WAG and be advised to take appropriate precautions to reduce exposures. Workers acutely exposed to excessive amounts of anesthetic gas can experience symptoms of drowsiness, headache, nausea, poor judgment and loss of coordination. Chronic symptoms of over-exposure can include liver, kidney and reproductive effects. Safety precautions include the use of an approved gas scavenging system, or using the agent inside a certified chemical fume hood.

Engineering Controls

Anesthetic gases should not be handled on the bench top without special ventilation or a scavenging system unless approved by EHS risk assessment. Anesthetic gas filtering cartridges, snorkel exhaust, fume hoods or other approved scavenging systems must be used. Fume hoods provide the best protection against exposure to anesthetic gases in the laboratory and are the preferred ventilation control device when handling liquid anesthetics outside of the original container.

Liquid anesthetics administered with a vaporizer must be scavenged. Passive scavenging via the use of charcoal canisters often results in elevated WAG exposures and should only be utilized when engineering controls and active scavenging systems are not feasible. Passive scavenging relies on the positive pressure of the anesthesia machine and the animal exhaling to push the anesthetic gas in to a charcoal canister for adsorption.

Charcoal canisters should always be upright and below the vaporizer of the anesthesia machine so that the heaviness of the waste gases is exploited. Canisters with exhaust ports on bottom must be configured such that the holes on the bottom of the canister are not blocked. Activated charcoal canisters only adsorb halogenated anesthetic gases (e.g. isoflurane, halothane). Immediately before using any anesthesia machine, the charcoal canister should be removed and weighed to evaluate the remaining adsorption capacity. Record the date and weight in grams on the side of the canister. Immediately following use, record the number of hours the canister was used next to the dated weight information.

Canisters that exceed 12 hours of use or 50 grams of accumulated weight (whichever comes first) must be removed and placed in a sealed plastic bag and disposed of as a hazardous waste.

Work Practice Controls

All anesthetic agents must be clearly labeled with the correct chemical name. Handwritten labels are acceptable; chemical formulas and structural formulas are not acceptable.

Do not permit containers to remain open on the bench top. The odor thresholds for most liquid anesthetics (except for ether) are well above permissible exposure limits. If you smell the anesthetic the control procedures you are using are inadequate and must be re-evaluated.

Always keep the flow rate of anesthetics to the animal as low as possible during the procedure. High flow rates can increase your exposure to the anesthetic. It is also important to move the point of potential gas release as close to the exhaust system as possible to increase capture of the chemical.

There are a variety of pathways for the gas to travel besides through the filter, which has a relatively high flow resistance. WAG can leak, particularly around the animal facemask or nosecone as well as when opening and closing induction chambers. It is important to attempt to seal all leaks to ensure there is a tight fit around the animal's nose and to flush out the induction chamber with oxygen for 20 seconds prior to unsealing the lid and retrieving the anesthetized animal. Quickly replace the lid of the chamber, and continue to run oxygen through the chamber for several minutes to help purge the WAG into the scavenger. Thoroughly clean the induction chamber immediately after each use to avoid residual WAG release into the environment (which can continue to be released for up to three hours).

The National Institute for Occupational Safety and Health (NIOSH) has a recommended exposure limit (REL) for halogenated anesthetic gases of 2 ppm as a ceiling limit (average over 1 hour). This may be below the human odor detection limit for isoflurane, so if you can smell it, the exposure level is too high. Contact EH&S to assess your surgical suite or work space to determine any risks of over exposure to WAG. EHS can also provide exposure monitoring to determine whether a worker may be over exposed to WAG.

Personal Protective Equipment (PPE)

Eye protection in the form of safety glasses must be worn at all times when handling anesthetic agents. Ordinary (street) prescription glasses do not provide adequate protection

Single use nitrile or latex gloves must be worn when handling anesthetic agents as well as lab coats, closed toed shoes and pants. Additional protective clothing should be worn if the possibility of skin contact is likely.

Transportation and Storage

Halogenated liquid anesthetic agents (i.e. halothane, enflurane, isoflurane) are not flammable but do have limited shelf life. Be certain to date the chemical when it is opened and to check expiration date before use.

Waste Disposal

Anesthetic agents are hazardous wastes. Contact EH&S at 672-1949 for waste containers, labels, manifests, waste collection and for any questions regarding proper waste disposal. Also refer to EHS's [Hazardous Waste webpage](#) for more information.

Exposures/Unintended Contact



If the employee is in need of emergency medical attention, call 911 immediately.



Wash hands and arms with soap and water immediately following any skin contact with anesthetic agents. Flush eyes for 15 minutes following eye contact.

Contact EH&S for advice on symptoms of chemical exposure, or assistance in performing an exposure assessment.

Report all work related accidents, injuries, illnesses or exposures within 24 hours by completing and submitting the [Report of Injury or Illness Form](#).

Spill Procedures

Anticipate spills by having the appropriate clean up equipment on hand. Spill materials for anesthetic agents are designed to control the liquid portion of the spill and minimize the production of vapors. Never use paper towels on large spills of anesthetic agents because it exacerbates vapor production.

- When a spill occurs, ***personal safety should always come first.***
- Alert and clear everyone in the immediate area where the spill occurred.

A **minor (small) chemical spill** is one that the laboratory staff is capable of handling safely without the assistance of safety and emergency personnel, i.e., less than 1 liter. A **major/large chemical spill** requires active assistance from emergency personnel.

Additional Steps for Spill Response:

MINOR CHEMICAL SPILL

- Alert people in immediate area of spill.
- If spilled material is flammable, turn off ignition and heat sources. Don't light Bunsen burners or turn on other switches.
- Open outside windows, if possible.
- Wear protective equipment, including safety goggles, gloves and long-sleeve lab coat.
- Avoid breathing vapors from spill.
- Confine spill to as small an area as possible.
- **Do not wash spill down the drain.**
- Use appropriate spill kits/sorbents to absorb spill. Collect contaminated materials and residues and place in container. Contact EHS-HMM (330) 672-1949 for proper disposal.
- Clean spill area with water.

MAJOR CHEMICAL SPILL

- Attend to injured or contaminated persons and remove them from exposure.
- Alert people in the laboratory to evacuate.
- If spilled material is flammable, turn off ignition and heat sources. Don't light Bunsen burners or turn on other switches.
- **Call 911 immediately for assistance.**
- Close doors to affected area.
- Post warnings to keep people from entering the area.
- Have person available that has knowledge of incident and laboratory to assist emergency personnel.

Report all emergencies, suspicious activity, injuries, spills, and fires by calling 911.

Training of Personnel

All personnel are required to complete the [Lab Safety: Chemical Safety Introduction](#). In addition, all personnel shall read and fully adhere to this SOP when handling animal anesthetics.

Certification

Use anesthetic gases in laboratory animals

I have read and understand the above SOP. I agree to contact my Supervisor or Lab manager if I plan to modify this procedure.

Name	Signature	Student/Employee number	Date

Major Revisions (*Tracking purposes only – Do not print as part of SOP*)

How to Safely Use Isoflurane in Animal Research

Typically, Isoflurane is administered to animals using one of these two methods:

VAPORIZER SYSTEM

In this method, liquid isoflurane is converted to a gas and mixed with oxygen to achieve the desired percent composition that is to be delivered to the animal. Waste anesthetic gas (WAG) scavenging is managed actively through the use of a vacuum exhaust, or passively through activated charcoal canisters.

Using a vaporizer system is effective for delivering a precise amount of isoflurane and when properly coupled with active or passive scavenging methods, minimizes WAG exposure. When using a vaporizer system, include the following safety precautions:

- Use an induction box that has a sliding lid instead of a hinged lid to reduce the amount of WAG released.
- Flush the induction box with oxygen for approximately 10 seconds prior to opening the box and retrieving the animal.
- Ensure that there is a tight seal around the animal's face when using a nose/face cone to deliver isoflurane.

OPEN DROP-JAR

This method uses a small container and absorbent material such as a piece of cotton gauze. Liquid anesthetic is placed on the absorbent material and placed inside the container. The animal is placed into the container and the lid is sealed while the liquid vaporizes. There is a high risk of WAG exposure using this method and therefore, whenever possible, you must perform this work within a chemical fume hood.

Additional steps to take to reduce your exposure when performing procedures using the Open-Drop jar method include:

- Use only for brief procedures lasting no longer than 1 minute
- Keep the jar at arms-length when opening
- Use the smallest amount of isoflurane needed to achieve intended results.
- Do not perform the work in a standard biosafety cabinet or laminar flow hood as they are not safe for use with volatile chemicals.

Additional Safety Practices

- Review the Use of Anesthetic Gases in Laboratory Animal Research document
- Customize this document to fit your lab's specific needs and post within lab.