

IACUC POLICIES AND PROCEDURES

AT

WRIGHT STATE UNIVERSITY

[Revised and Approved March 2024]

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MISSION STATEMENT

Wright State University recognizes the scientific and ethical responsibility for the humane care and use of animals involved in research, education, and testing and enjoins all individuals involved to the highest standards of care and consideration.

Animal, as defined anywhere in the Policies and Procedures document, will be all vertebrate animals involved in research, testing, and teaching.

The Institutional Animal Care and Use Committee, as agent for Wright State University's obligations for humane care and use of animals, shall:

- 1) Assure all activities (involving animals) meet the ethical and legal requirements for the humane care and use of animals.
- 2) Maintain and promote an open and cooperative relationship with investigators and faculty, and the greater university community.
- 3) Educate the Wright State University community concerning the ethical and regulatory considerations for the humane care of animals.

The Wright State University Institutional Animal Care and Use Committee considers it a moral and ethical obligation to educate our community, both internal and external, on the importance of animals for research and teaching.

GENERAL COMMITTEE STRUCTURE

Membership: Members are appointed by the Institutional Official (Vice President for Research and Graduate Studies) and the appointment is confirmed by the President of Wright State University and the Board of Trustees. Membership must include at least:

1. Veterinarian/LAR Director
2. Community Representative
3. Non-scientific Representative
4. Two other members representing the wide diversity of activities utilizing animals at Wright State University, one of which is a scientist with animal research experience.
5. A Veterans Affairs Medical Center Representative

Alternate members are designated to represent specific member types (e.g., scientist, non-scientist, community representative) when any member of that type is absent from a meeting. Alternates may attend all meetings but may only count toward a quorum and vote in the absence of that type of member.

The Chair is appointed by the Institutional Official.

The Vice-Chair is appointed by the Institutional Official after recommendation from the Chair with concurrence of the Committee. The Vice-Chair is authorized to assign primary reviewers to new animal use petitions, chair IACUC meetings, sign action forms, and perform other functions in the absence of the Chair or in cases of potential conflicts of interest involving the Chair.

Qualifications for Members:

1. Commitment to the ethical and scientifically sound conduct of research, teaching or testing involving animals.
2. Complete all required training for IACUC members.
3. Thorough review of pertinent documents concerning appropriate animal care for research, teaching, and testing activities at WSU.

Meetings: Meetings are open to the public. Matters concerning personnel, security arrangements, conferences with the University General Counsel (or other attorney from this office), or issues required to be confidential by federal, state or local law may be held in executive session. Meetings must, however, be convened and adjourned in public session.

Regular meetings are scheduled monthly, with additional meetings called by the Chair as deemed necessary.

While the committee actively works to reach consensus on issues presented for consideration, the Committee does function from a majority rule. To further evidence diversity of opinion, Minority Opinions are called for in the Semi-Annual Reports and any dissenting or abstained vote is included in the minutes of all meetings. Any submitted Minority Opinions will be included in the minutes

ALTERNATE IACUC MEMBERS RESPONSIBILITIES

1. Alternates are appointed in the same manner (i.e., by the Institutional Official, with confirmation by the President and Board of Trustees) and receive the same training as Voting members.
2. Alternate members are appointed to represent specific member types (e.g., scientist, non-scientist, community representative) and this appointment is based on criteria similar to that used to appoint the Voting members of that type.
3. IACUC Alternates and their Voting member may not contribute to a quorum at the same time or act in an official IACUC-member capacity at the same time (i.e., an Alternate may only contribute to a quorum and function as a voting IACUC member if one of the Voting members in a particular member type for whom they serve as alternate is unavailable).
4. Alternate members are, however, encouraged to attend IACUC meetings and participate in all other IACUC activities (e.g., review of protocols and/or amendments, discussion of protocols, and serve on subcommittees for inspections and investigations of non-compliance) provided a conflict in voting responsibilities does not occur between Alternate and Voting members.

SUBMISSION OF ANIMAL PROTOCOLS

1. Electronic Submissions and Notifications
 - a. To the extent possible, Committee business will be conducted electronically through the RSP Gateway at <https://rspgateway.wright.edu>, or other software approved by Research and Sponsored Programs.
 - b. Prior to conducting any electronic business with the Committee, it is recommended for first-time users to attend a training session provided by RSP. Information about gaining access to RSP Gateway and starting an RSP Gateway protocol can be found at <http://www.wright.edu/research/compliance/animal-welfare>.
 - c. The “Animal and Biosafety” tab in the system allows for the submission and routing of new petitions, amendments, and annual reports.
 - d. The RSP Gateway system provides on-line e-forms with the ability to allow investigators to save partially completed actions for completion/review/modification at a later time, and allows investigators to modify actions per committee requests.
 - e. If a document is submitted electronically on a deadline date, it will be deemed to have met the deadline. Application deadlines and IACUC meeting schedules are established well in advance.

GENERAL IACUC REVIEW/APPROVAL PROCEDURES

1. Methods of application review
 - a. The procedural review requirements of the Public Health Services (PHS) Policy and/or Animal Welfare Regulations (AWRs) are followed in all IACUC review procedures.
 - b. The PHS Policy and AWRs recognize two methods of application review: Full Committee Review (FCR) and Designated Member Review (DMR). The IACUC can conduct application reviews using the DMR method or a Full Committee Review (FCR), provided such reviews are done in accordance with the Public Health Service (PHS) policy.
2. New protocol applications are typically reviewed by Full Committee Review while amendments are usually conducted by Designated Member Review.
3. Revised protocols that have been approved pending receipt of clarifications not involving major changes may be recommended for approval after being reviewed for adequate response by the Chair plus one other IACUC member (usually the Veterinarian) with notification of the IACUC. All IACUC members have agreed **in writing** that the quorum of members present at a convened meeting may decide by unanimous vote to use Designated Member Review subsequent to Full Committee Review when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request full committee review of the protocol.
4. The effective start date for new protocols and amendments will be the date of electronic approval by the IACUC Coordinator.
5. Closures of protocols are carried out by Research and Sponsored Programs (RSP) with notification to IACUC, the Principal Investigator, the PI's Department Chair, and Laboratory Animal Resources.
6. The transfer of animals from one approved protocol to another approved protocol must be approved by the IACUC as part of the approved protocol (i.e., either at original review or by amendment).

PROCESSING NEW ANIMAL USE PROTOCOLS

I. Veterinarian Review and Consultation:

As part of the submission process in the RSP Gateway, protocols will be reviewed by a veterinarian. This review, at a minimum, will cover the appropriateness of the animal model, procedures expected to cause pain and/or distress, pre-operative and post-operative care, the inclusion of appropriate endpoint criteria, and euthanasia. Other aspects of the proposed protocol may be identified and discussed. Outcomes of this review and consultation may be:

- A. The Veterinarian Approves: The Veterinarian will indicate the protocol is adequate and it may be forwarded to the Office of Research and Sponsored Programs (RSP) (Section II of this procedure).
- B. The Veterinarian makes recommendations for changes to be made to the protocol and routes the petition back to the investigator. The investigator should consider carefully the recommendations of the Veterinarian, and modify the protocol as appropriate. The Veterinarian then approves the protocol.
- C. After review of the protocol, if the Veterinarian believes that the Institution is unable to support the research protocol for any reason, approval may be withheld. The veterinarian may still submit this protocol to RSP for review.

II. Protocol Receipt and Initial Processing

Following veterinary review and editing of the protocol by the investigator, the protocol will electronically route to the appropriate department chair for review followed by the Institutional Animal Care and Use Committee (IACUC) chair. The IACUC chair will assign a primary reviewer to present the protocol to the IACUC if the protocol will be reviewed during a full committee meeting, or will designate reviewers if the protocol will be reviewed via Designated Member Review (DMR).

III. Animal Use Protocol (AUP) Review:

There are two methods of review that the IACUC may use, Full Committee Review (FCR) and DMR. The specific method of review for a given protocol must be documented, along with the outcome of the review.

A. Full Committee Review (FCR)

FCR may only be used for AUP review during meetings with a convened quorum. Any AUP may be reviewed using FCR, using the following procedures:

- 1. Prior to each IACUC meeting, all members will receive an agenda with electronic links to AUPs to be reviewed. Committee members should review the protocols prior to the meeting and may notate concerns directly on the petition for other committee members to see, or may contact the primary reviewer separately with those concerns. The primary reviewer may act as a liaison between the IACUC members and the PI to address questions/concerns.

2. At the next IACUC meeting the primary reviewer presents a short synopsis of the protocol followed by a discussion of the protocol. Any committee member present may express questions or concerns for committee discussion.
3. After the protocol is completely discussed, the reviewer makes a motion to do one of the following: Approve the protocol as written; Require modifications (to secure approval); Withhold approval. Protocols that lack substantive information necessary for the IACUC to make a judgement are deferred review until additional information is provided by the investigator. All IACUC members have agreed in advance, in writing, that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol. In general, DMR of modifications/clarifications required to secure approval will be recommended if the committee considers the requested clarification(s) sufficiently minor and straightforward.

B. Designated Member Review (DMR)

AUPs that do not include potentially painful or distressful procedures may be reviewed using DMR. A protocol that proposes survival or terminal surgery, tumor studies, or death or moribundity as an endpoint requires FCR. Wright State University pain category C or D protocols require FCR.

Under exceptional circumstances, including periods of institutional or community emergency (such as natural disaster or pandemic infectious disease outbreak) as designated by the Wright State University Provost or applicable subcommittee, DMR may be used to review any AUP or amendment.

The following procedures will be followed when utilizing DMR for IACUC Initial Applications:

1. The IACUC chair will appoint at least two designated member reviewers for each protocol. If the chair is unavailable or has a conflict of interest, the vice-chair may appoint the designated member reviewers. If both the chair and vice-chair are unavailable for an extended period of time, the IACUC administrator may appoint the designated member reviewers.
2. All members will receive a secure, electronic link to the AUP to be reviewed by DMR. There will be a 7-day review period during which time any member may request that the protocol be reviewed using the FCR method. If any member requests FCR, then that method must be used.
3. During the review period any committee member may make comments electronically on the AUP form for other committee members and the designated reviewers to consider.
4. DMR may result in approval, a requirement for modifications (to secure approval), or referral to the full committee for review. DMR may not result in withholding of approval.
5. The designated reviewers must be unanimous in any decision. They must all review identical versions of the protocol and if modifications are requested by any one of the reviewers then the other reviewers must be aware of and agree to the modifications.

6. Such DMR shall be followed by notification of the outcome to the full Committee at the next IACUC meeting.

C. Amendments

Amendments will generally use the DMR process unless FCR is required by federal regulations or these policies and procedures. Any protocol that seeks to change its pain category through amendment to include unrelieved pain or distress will automatically be reviewed by FCR.

DMR of amendments involves review by a subcommittee of at least two IACUC members following distribution of a full copy of the requested action and supplemental material to all IACUC members with allowance of sufficient time to request FCR (e.g., three [3] working days). If no member requests FCR, then the requested action will be reviewed by DMR as previously described.

D. Administrative Changes

Changes that may be handled administratively without IACUC approved policies, consultations, or notifications include correction of typographical errors, correction of grammar, contact information updates, deletion of personnel (other than the PI), and deletion of procedure areas.

IV. Outcomes of IACUC Actions:

A. If the protocol is recommended for approval:

1. The IACUC chair will recommend approval electronically, and the system will forward it to the IACUC Coordinator for review and full approval. Note: Final approval requires the approval of the IACUC Coordinator.
2. The PI is notified of the outcome of the review.

B. If the protocol is sent to designated review with modifications/clarifications required to secure approval:

1. An email requesting modifications/clarifications will be sent to the investigator via the RSP Gateway, and the investigator will be asked to respond. The IACUC will consider a protocol withdrawn if a timely response is not received within 90 days.
2. Upon receipt of the modifications/clarifications, the Chair plus one other IACUC member (preferably the Veterinarian or alternate Veterinarian) will review the response and either indicate that it is adequate and proceed as in Section IV.A., request further clarification, or request that the response be sent to the full committee as in Section III., as appropriate (See Section IV.E.)
3. The PI is notified of the outcome of the review.

C. If the protocol review is deferred:

1. The PI will be notified of the action and reasons for the action. If additional information or clarifications are requested, the PI will be asked to respond within 90 days. The IACUC will consider a protocol withdrawn if no response is received within 90 days.
2. Upon receipt of the PI's response, the revised protocol will be reviewed by full committee at the next meeting as previously described.

D. If approval withheld (outcome possible only following full IACUC review):

1. The PI will be notified of the action and the reasons for the action.
2. Although PIs will be given the opportunity to respond to this action, in general, if approval is withheld, the protocol will be withdrawn.

E. Regardless of the nature of the changes or modifications requested in Section IV.B. or Section IV.C., clarifications, responses to restrictions, or other requested changes shall be incorporated into a revised protocol with the revision(s) highlighted. This revised document will be the protocol of record.

V. Effective Start Date for New Protocols and Amendments

The effective start date for new protocols and amendments will be the date of electronic approval by the IACUC Coordinator

VI. Three-Year (de novo) Review of an Active Protocol

The three-year review of a protocol will be conducted as a "New" protocol following the "Three (3) Year Review Policy"

FORMAT FOR SUBMITTING PROTOCOLS

Petitions to the IACUC regardless of source (e.g., internal or external users) must be made using the petition form currently approved by the IACUC.

Protocols requiring review by animal care committees at Department of Defense (DoD) locations (e.g., Wright Patterson Air Force Base) may need to be submitted to that DoD committee using a format prescribed by DoD. In these situations, Wright State principal investigators who also need IACUC review and approval of the same protocol must submit the DoD-prescribed form to the IACUC and the WSU petition form. Similarly, investigators with Veterans Affairs Medical Center funding will also have to fill out both animal protocols (VA and WSU).

RENEWAL NOTIFICATIONS

For *de-novo* renewals, the PI will be notified by the RSP Gateway that a *de-novo* submission is due at least three (3) months prior to its date of expiration (Triennial Review Date). The PI will be sent subsequent notifications two (2) months, and one (1) month, prior to the expiration date. The PI must submit the *de-novo* submission with adequate time that the IACUC can review the petition at a regularly scheduled meeting, respond to the committee's restrictions, and obtain approval from the IO prior to the expiration date. Failure to submit a timely *de-novo* submission will result in animals being transferred to the LAR Holding Protocol during which time the animals cannot undergo any experimental manipulations. Only regular housing and husbandry care will be conducted while on the Holding Protocol until the *de-novo* submission receives final approval from the IO.

ANNUAL REVIEW OF PROTOCOLS

Annual reviews will occur of protocols as required by the funding agency, or as deemed necessary by the IACUC, during post-approval monitoring activities. Responses are evaluated by an IACUC subcommittee, and then presented to the IACUC for review. Disposition of the review will be documented as an official IACUC action.

REPORTING THE MISTREATMENT OF ANIMALS AND DEFICIENCIES AT WRIGHT STATE UNIVERSITY

It is the policy of Wright State University that the care, use, and treatment of university-owned laboratory animals should be of high quality and in compliance with all federal, state, and local regulations. The law requires that all persons involved or in any way associated with the use of animals in research know how to report deficiencies in animal care and treatment. There are no restrictions on who can report an alleged incident. Anyone who has knowledge of such a deficiency is obligated to report it to the proper Wright State official immediately. Under no circumstances will reporting such incidences in good faith be detrimental to an individual's standing within the organization.

1. DEFINITION: Allegations of animal mistreatment or deficiencies in care include the following:
 1. The wrongful or abusive physical or psychological treatment of an animal.
 2. Non-compliance with established procedures, policies or approved protocols.

An Adverse Event is defined as an event which negatively impacts animal well-being, harms or poses a threat of harm to an animal. Additional information about adverse event reporting can be found in the IACUC policy, Adverse Event Assessment and Reporting Plan.

2. PROCEDURES: Any person with knowledge of deficiencies or with reasonable suspicions of deficiencies or mistreatment involving Wright State University laboratory animals is obligated to report them directly to the Chair of the Wright State University Institutional Animal Care and Use Committee (IACUC), any member of the IACUC, the Director of Laboratory Animal Resources (LAR) 937-775-2792, or the Institutional Official 937-775-3336. Contact telephone numbers for these individuals are posted in animal facilities. Timely reporting is essential to protect the animals involved and to aid the investigation of the allegations. Persons may report animal care and use concerns anonymously by calling the EthicsPoint Toll-Free hotline at **1-855-353-3783**, or by using the EthicsPoint link available on the Research and Sponsored Programs Research Compliance or Animal Welfare website.
 - a. Neither administrative action nor retribution of any kind may be taken against a person making a good faith report of deficiencies. This is in accordance with public law [9 CFR, Part 2, Subpart C 2.32 (c) (4)].
 - b. Any person reporting a concern or deficiency will be treated in a nondiscriminatory manner. The identity of the individual making the report remains confidential in most cases.
 - b. Reports of suspected deficiencies should be made in writing whenever possible and should include, but need not be limited to, the nature and the place of the occurrence, the alleged person or persons involved, the date, the time, and any supporting facts.

- c. If a person actually witnesses mistreatment or abuse, the witness will immediately notify the Veterinarian in charge of the LAR at x2792, the IACUC Chair or the Institutional Official at x3336, so that the animal or animals involved can be evaluated and receive medical treatment if necessary. The person should then report the incident through channels as described above.
 - d. The Institutional Animal Care and Use Committee will investigate allegations and report its findings and recommendations to the Institutional Official in a timely fashion.
3. Details of any reports or allegations of deficiencies, findings or recommendations of the Institutional Animal Care and Use Committee, as well as administrative or legal actions taken by the committee are considered privileged information and may be released only through official channels, or as required by law.
4. Willful mistreatment or abuse of animals may be grounds for suspension of all animal use activities or approved protocols involved, or other disciplinary actions. Disciplinary action may be appealed.
5. This policy (Reporting the Mistreatment of Animals and Deficiencies at Wright State University) will be distributed to all personnel involved in any way in animal research at or through WSU facilities during Introductory Animal Care and Use training sessions. Personnel attending these sessions are required to acknowledge that they have received and understand this information. Principal investigators will be responsible to assure that all personnel involved in research activities under their direction are aware of the above procedures.
6. Statutory authority for this policy is found in the 1985 Amendment to The Animal Welfare Act Title 7, United States Code, Section 2131-2156, PL-99-198. The act requires that "...training for scientists, animal technicians, and other personnel involved with animal care...shall include...methods whereby deficiencies in animal care and treatment should be reported."

PROCEDURES FOR DEALING WITH ALLEGATIONS OF ANIMAL MISTREATMENT OR DEFICIENCIES IN THEIR CARE AT WRIGHT STATE UNIVERSITY

PURPOSE: The purpose of this procedure is to establish guidelines for the investigation of complaints alleging the mistreatment of animals or other deficiencies in animal care or treatment.

DEFINITION: Allegations of animal mistreatment include the following: 1. The wrongful or abusive physical or psychological treatment of an animal. 2. Non-compliance with established procedures or policies.

REPORTING: Allegations should be made in writing, when possible, to the Chair (or to any member) of the IACUC or to the Institutional Official. In all instances these allegations shall be immediately forwarded to the IACUC Chair. There are no restrictions on who can report an alleged incident. In accordance with the public law [9 CFR, Part 2, Subpart C 2.32(c) (4)], under no circumstances will reporting such incidences be detrimental to an individual's standing within the organization. Instruction regarding the methods by which allegations may be made to the IACUC and whistle-blower protection will be outlined in mandatory investigator training sessions. In addition, these instructions will be posted on bulletin boards in each building where research animals are used.

IACUC PROCEDURES FOR THE INVESTIGATION OF A COMPLAINT: The IACUC Chair is responsible for the receipt and disposition of all complaints. All allegations will remain confidential to the extent possible until proven or disproven. When the complainant wishes to be openly identified, the IACUC Chair will acknowledge receipt of the allegation to the complainant in writing. The IACUC Chair will present all allegations either to a convened subcommittee or to the IACUC during its next meeting. The IACUC or subcommittee will then determine if the complaint has sufficient substance to warrant a full investigation and then determine the procedures by which it will carry out an investigation. All persons involved in the investigation will be informed verbally or in writing of the purpose of the investigation and the manner in which it will be conducted. **If there is indication of serious noncompliance, the IACUC may, with the concurrence of the Institutional Official, suspend an activity pending the outcome of a full investigation.** The IACUC will examine all pertinent documents, animals, procedures, and interview involved personnel during its investigation. Persons against whom the complaint is made will be given the opportunity to appear before the committee. The final result(s) of the investigation will be presented in executive session during a formal meeting of the IACUC and all committee members will be given the opportunity to present minority views. The IACUC will inform all parties involved, including the complainant, of the committee's findings.

The results will be forwarded to the Institutional Official with appropriate recommendations.

- a. If following an investigation of the alleged incident the IACUC finds no evidence of animal mistreatment or noncompliance, the report of the investigation will be forwarded to the Institutional Official with the recommendation that no further action be taken.
- b. If allegations of animal mistreatment are substantiated, the Institutional Official will be advised of the committee's findings and recommendations. The Institutional Official will then take appropriate action after consulting with the IACUC and reviewing the results of the IACUC investigation. The Institutional Official has the power to impose sanctions on an investigator found responsible for mistreatment or noncompliance. The decision of the Institutional Official is final.
- c. The IACUC, through the Institutional Official, will promptly provide OLAW (and USDA, if appropriate) with a full explanation of the circumstances and actions taken with respect to:

1. Any serious or continuing noncompliance with the PHS policy.
2. Any serious deviations from the provision of the *Guide*.
3. Any recommendation of suspension of an activity by the IACUC to the Institutional Official.
4. Recommendations to prevent further occurrences.

ADVERSE EVENT ASSESSMENT AND REPORTING PLAN

1. Purpose

This policy seeks to define Adverse Events and identify the reporting responsibilities for animal use protocol-related and non-protocol-related adverse events. Reporting significant adverse events fosters protection of the integrity and creditability of the institution and demonstrates a culture of care. Prompt reporting allows an institution to evaluate whether the single incidents over time collectively indicate a more significant concern. This policy describes the procedures to take when an adverse event occurs, and identifies when the reporting of Adverse Events or Unexpected Outcomes to regulatory agencies is necessary.

2. Definition

An **Adverse Event**, for the purposes of this policy, is defined as any event which negatively impacts animal well-being, harmed or posed a threat of harm to a vertebrate animal, and which meets one or more of the following conditions:

- a. The event occurred during research-related, teaching or demonstration, but was not identified in the approved protocol.
- b. The event occurred at a rate or severity higher than indicated in the approved protocol.
- c. The event was not research-related, but was due to a facility, physical plant, equipment, or personnel failure, malfunction, or mistake.

3. Types of Events to Report

- a. Examples of adverse events which must be reported include, but are not limited to:
 - Genetically modified or mutant animals that manifest a phenotype that negatively affects animal well-being;
 - Physical restraint of an animal that results in lesions, illness, or behavioral changes.
 - A surgical procedure that results in unexpected complications.
 - Morbidity or mortality rates higher than described in the protocol, regardless of the reason.
 - Failures in HVAC systems, automatic feeders, or watering systems.
 - Adverse experimental surgical outcomes that were not anticipated in the protocol.
 - High levels of “cluster” morbidity or mortality, a grouping of animal illnesses or deaths occurring closely together, above anticipated incidence.
 - Any unexpected animal death or injury
 - i. Animal death or illness from spontaneous disease when appropriate quarantine, preventive medicine surveillance, diagnostic, and therapeutic procedures were in place and followed.

- ii. Animal death or injuries related to manipulations that fall within parameters described in the IACUC approved animal care and use proposal.
- b. Examples of adverse events which are not required to be reported include:
 - Death or morbidity of animals as described in the approved animal use protocol.
 - Mortality resulting from surgical complications anticipated in the approved protocol, at or below the anticipated rate.
 - Injury/illness unrelated to approved procedures and being treated by the veterinarian.
- c. Examples of potential resolution plan modifications which might be requested in response to an adverse event report include, but are not limited to:
 - Change in anesthetic
 - Procedural modifications
 - More frequent monitoring intervals
 - Additional or more timely humane endpoints
 - Updated description of expected or likely adverse outcomes in the approved protocol

Note: Changes in procedures will require that the PI submit a protocol amendment to the IACUC

4. Procedures

- a. It is the responsibility of the Principal Investigator (PI) to promptly report adverse events via email, phone or in person to the veterinarian. This allows an immediate response to take place when necessary to prevent further adverse events from occurring. The veterinarian will determine the impact of the adverse event and if the IACUC should be notified so that a resolution plan may be developed to ensure animal well-being.
- b. If the veterinarian determines that an adverse event or unexpected outcome has occurred, then the adverse event report form should be completed by the PI and submitted promptly to the IACUC administrator through SecureShare or another secure file sharing service.
- c. The IACUC will review Adverse Event Reports at monthly meetings to identify potential problem areas or trends that merit attention. The IACUC will review proposed corrective plans and may require the investigator to take further actions.
- d. The IACUC will determine if additional formal reporting to regulatory agencies is necessary.
- e. Any actions taken or requirements made regarding a research-related adverse event will be reported to the PI by the IACUC administrator.

5. Reporting to Regulatory Agencies

IACUC reporting to regulatory agencies should be based on the following:

OLAW	
<p>Preliminary and final reports should be made to: Director, Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health Rockledge 1, Suite 360, MSC 7982 6705 Rockledge Drive Bethesda, MD 20892-7982 Phone: 301-594-2061 FAX: 301-402-2803 E-mail: olawdco@mail.nih.gov</p>	
When to Report	Event
<p>Report Promptly</p> <p>Make preliminary report by phone or email as soon as possible</p> <p>Include as much information as possible in the initial contact with OLAW.</p> <p>Send final thorough report after IACUC investigation and review at full IACUC meeting, and after action has been taken.</p> <p>The final report addresses anything not known at the time of the initial report and summarizes the institution's corrective action. If a long-term plan is necessary, describe the plan and include a reasonable schedule.</p>	<ul style="list-style-type: none"> • Any serious or continuing noncompliance with PHS Policy • Any serious deviation from the provisions of the Guide • Any suspension of an activity by the IACUC (report also to federal funding agency supporting the activity) • Unexpected animal death • Adverse Events (examples): <ul style="list-style-type: none"> ○ Conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals ○ Conduct of animal-related activities without appropriate IACUC review and approval ○ Failure to adhere to IACUC-approved protocols; ○ Implementation of any significant change to IACUC-approved protocols without prior IACUC approval ○ Conduct of animal-related activities beyond the expiration date established by the IACUC (note that a complete review is required at least once every three years) ○ Conduct of official IACUC business requiring a quorum in the absence of a quorum ○ Conduct of official IACUC business during a period of time that the Committee is improperly constituted ○ Failure to correct deficiencies identified during the semiannual evaluation in a timely manner ○ Chronic failure to provide space for animals in accordance with recommendations of the Guide (unless the IACUC has approved a protocol-specific deviation from the Guide based on written scientific justification) ○ Participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained

	<ul style="list-style-type: none"> ○ Failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures) ○ Failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry) ○ Failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO₂) ○ Failure of animal care and use personnel to carry out veterinary orders (e.g., treatments) ○ IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the Guide, or the institution's Animal Welfare Assurance
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USDA	
Contact area VMO inspector or the Animal Care office E-mail: animalcare@usda.gov Phone: (970) 494-7478 Fax: (970) 494-7461	
When to Report	Event
Report Promptly to APHIS and any federal agency funding the activity with full explanation	<ul style="list-style-type: none"> ● Any suspension of an activity by the IACUC
Report in writing within 15 business days to APHIS and any federal agency funding the activity	<ul style="list-style-type: none"> ● Report failure to adhere to the plan and schedule for correcting a Significant Deficiency (which is or may be a threat to the health or safety of the animals)
Report promptly	<ul style="list-style-type: none"> ● Unexpected animal deaths
Call VMO to report/discuss within 5 days of the event, whether noncompliance is suspected or not.	<ul style="list-style-type: none"> ● Adverse events

AAALAC International	
Send written notification by email to accredit@aaalac.org Or the unit contact can report online https://www.aaalac.org/unit-login/adverse-event-report Include Unit ID 000869 in subject line of email.	
When to Report	Event
Report in Annual Report	<ul style="list-style-type: none"> ● Protocol violations which had the potential to compromise animal welfare ● Animal use not approved by the IACUC or comparable oversight body ● Significant adverse events not previously reported as required by the Rules of Accreditation

<p>Report Promptly</p>	<ul style="list-style-type: none"> • Inadequate veterinary care • Conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals • Significant animal rights activities (e.g., protests, break-ins, property damage, FOIA and other public records requests that include AAALAC International documents) • Inappropriate euthanasia techniques and/or failure to confirm euthanasia • Substantiated complaints or reports regarding animal welfare concerns • Internal or external reviews/inspections or reports that document significant adverse events or noncompliance that resulted in animal harm or death • Other serious incidents, unexpected outcomes, or concerns that negatively impact animal well-being <ul style="list-style-type: none"> ○ Failure to follow the approved protocol which resulted in compromised animal welfare ○ Death during transport ○ Genetically modified or mutant animals that manifest a phenotype that negatively affects animal well-being; ○ Physical restraint of an animal that results in lesions, illness, or behavioral changes. ○ A surgical procedure that results in unexpected complications. ○ Morbidity or mortality rates higher than described in the protocol, regardless of the reason. ○ Adverse experimental surgical outcomes that were not anticipated in the protocol. ○ High levels of “cluster” morbidity or mortality, a grouping of animal illnesses or deaths occurring closely together, above anticipated incidence. ○ Any unexpected animal death or injury ○ Animal death or illness from spontaneous disease when appropriate quarantine, preventive medicine surveillance, diagnostic, and therapeutic procedures were in place and followed. ○ Animal death or injuries related to manipulations that fall within parameters described in the IACUC approved animal care and use proposal. • Investigations by national oversight bodies • Significant human health issue directly related to the animal care and use program
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Dayton VA Medical Center

Contact the Administrative Officer of the Dayton VA

Phone: 937-262-2194

Nicholas.McCray@va.gov

When to Report	Event
<p>Within 2 business days of receipt of information, even if IACUC investigation of the matter is still pending.</p> <p>Notify VA immediately of outcomes of investigations of any matter that is potentially reportable</p>	<ul style="list-style-type: none">• Receipt of any complaint, allegation, or other information suggesting concerns about animal welfare or potential regulatory noncompliance <i>relevant to the Collaboration</i>• The outcome of any investigation by the IACUC regarding any matter that is potentially reportable <i>and relevant to the Collaboration</i>

6. References

“FAQs.” *AAALAC*, AAALAC International, June 2022, www.aaalac.org/accreditation-program/faqs/#H2.

“Not-OD-05-034: Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals.” *National Institutes of Health*, U.S. Department of Health and Human Services, 21 Feb. 2013, grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html.

National Research Council (US) Committee for the Update of the Guide for the Care and Use of Laboratory Animals. *Guide for the Care and Use of Laboratory Animals*. 8th edition. Washington (DC): National Academies Press (US); 2011. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK54050/> doi: 10.17226/12910.

“Animal Welfare Act and Animal Welfare Regulations.” *USDA Aphis | Home Landing Page*, www.aphis.usda.gov/animal_welfare/downloads/AC_BlueBook_AWA_508_comp_version.pdf.

IACUC SERVES AS THE IACUC FOR THE VAMC DAYTON

*This is included here as a reference. Please see the MOU for the most up-to-date terms of this agreement.

Wright State University IACUC will be the IACUC of record for the Dayton Veterans Affairs Medical Center.

Review Procedure:

1. Protocol format
 - a. A tracking number will be assigned to the protocol.
 - b. The WSU IACUC will review the WSU animal protocol form. Any information that is required on the VA (ACORP) form but not on the WSU IACUC form will be provided as an appendix or otherwise included for review and approval as part of the protocol. A VA protocol will also be filled out and submitted to the IACUC.
2. The Dayton VAMC will assign a representative to be a full member of the WSU IACUC. This member will be appointed by the WSU institutional official as described in the Committee Structure section above. The VAMC representative on the WSU IACUC serves as liaison and is authorized to communicate freely with the VAMC regarding any action of the WSU IACUC.
3. A memorandum of understanding (MOU) has been signed which defines the expectations of Wright State University and the Dayton VAMC with regard to their collaboration of the use of animals in research, in order to promote scientific collaboration, while reducing duplication of effort, ensuring regulatory compliance, and maintaining quality animal care and high standards of ethical conduct.
4. Wright State University agrees to inform the VAMC of any IACUC action pertinent to VAMC research with animals. This includes, for example, prompt verbal notification when a potentially reportable matter has come to the attention of the WSU IACUC, even if IACUC investigation is still pending. If a complaint, allegation, or other information suggesting concerns about animal welfare or potential regulatory noncompliance relevant to the Collaboration between Wright State University and the Dayton VAMC, the other party will be notified within two business days of receipt of the information, even if IACUC investigation of the matter is still pending.
5. All other procedures and policies for the Wright State IACUC will apply to Dayton VAMC protocol submission, review, operation, and management.

TIME LIMITATIONS FOR VARIOUS IACUC RESPONSE REQUESTS

Notification of due dates for protocol renewal (i.e., three year *de novo* review) will be sent electronically to investigators at least three (3) months prior to the review or expiration date.

The committee recommends at least two notifications for investigators to respond to:

1. Requests for new petitions
2. Responses to requests for clarification or additional information following protocol or amendment reviews by the IACUC.

The IACUC will consider a protocol withdrawn if a timely response is not received within 90 days. Investigators will be promptly notified of this final action.

POLICIES

DETERMINING ANIMAL-USE REQUIREMENTS

Acquisition of Live Vertebrate Animals

Use (including housing or holding) of all live, vertebrate, laboratory animals, whether for research, teaching, or testing must be authorized by an active animal use protocol approved by the Wright State University Laboratory Animals Care and Use Committee (IACUC). To assure that all laboratory animal use is covered by an appropriate animal use protocol:

- A) All ordering of live vertebrate animals shall be done by Laboratory Animal Resources (LAR). The LAR will only assign these animals to, and allow their use in, active protocols approved by the IACUC.
- B) Transfer of all animals between active animal use protocols will be done by the LAR and IACUC as described in the IACUC "Disposition Policy".
- C) LAR must be notified of all other acquisitions of live vertebrate animals (for example by trapping or seining). These animals may only be acquired if their use is covered by an active animal use protocol approved by the IACUC.

Animal Activities Requiring a Protocol

All use of live animals and animal tissues must be covered by an approved protocol except:

- 1. When no live vertebrate animals are used and
- 2. When no vertebrate animals are euthanized for the specific proposed use.

“Live” Animal Determinations

Age when MAMMALS are considered live animals

Fetuses of mammals will be considered “live animals” for compliance and logistics purposes at the live birth of such animal(s).

Age when AVIANS are considered live animals

The IACUC shall consider avians subject to review as live vertebrates after 85% of the normal gestation period of the species’ eggs have passed.

Age when AMPHIBIANS are considered live animals

The IACUC shall consider amphibians subject to review as live vertebrates at the time the species require an external food source.

Animal models Requiring IACUC Review

Although non-mammalian vertebrates are not covered by the Animal Welfare Act, they are covered under the “Public Health Service Policy on the Humane Care and Use of Laboratory Animals” which we have adopted for all laboratory animals used for research, teaching, and testing at Wright State University. Any use of animals without an approved protocol is a serious breach of the University’s agreement with the Public Health Service upon which NIH funding of University research and teaching is dependent.

Therefore, non-mammalian vertebrates (i.e. fish and reptiles) used for research, teaching, or testing purposes must be covered by an approved animal use protocol. Though the use could be as casual as only observing the animals in a classroom or in research, an approved protocol is still required.

Activities for which the primary purpose is exhibition or demonstration of animals (outside of research, testing or education) will require neither submission of an animal use protocol nor notification of the IACUC.

The University’s Veterinarian, and Laboratory Animal Resources Director, is available for consultation regarding any protocols.

Proposed Activities Involving the Use of Laboratory Animals and/or Tissue

It is the goal of the Institutional Animal Care and Use Committee (IACUC) to ensure the proper and humane care and use of laboratory animals at Wright State University while not unnecessarily burdening Wright State University investigators. An investigator should call the LAR (x2792) to speak with the veterinarian about whether an animal use protocol will be needed for a proposed activity.

General Considerations. In general, an approved protocol is required for any use of live animals or of animal tissues/products for which an animal was expressly used. This would include, for example, use of an animal to obtain an organ or to produce an antibody. A protocol would not be required to use excess tissue from an animal that was euthanized for another purpose. This might include the removal of an organ from an animal sacrificed under an approved protocol. Similarly, a protocol is not required for use of tissues from livestock euthanized for food at a slaughterhouse. A critical point in determining that a protocol is not required in the latter cases is that tissue which would normally be unused is collected from an animal whose sacrifice is fully justified and approved for another purpose. An IACUC exemption request (available as an e-form) should be filled out to determine if an activity is exempt or requires an animal use protocol.

The production of animals or specific animal products (such as custom antibodies) at a non-WSU facility must be done under an approved protocol at that facility before those animals or animal products can be purchased by a WSU investigator.

ADOPTION OF A COMPANION PET

WSU's Adoption Policy

It is the purpose of this policy to allow dogs, cats, and other animals that are not now nor any longer assigned to protocols to be adopted by individuals as companion pets. For adoption to occur, several conditions must be met:

- A) The animals eligible for adoption must have no sign of compromised health either natural or experimentally derived. The Laboratory Animal Resource of Wright State University (LAR) will examine animals that are adoption candidates and determine their health status. Though the good health of an animal is a prerequisite for adoption, Wright State University will not guarantee adopted animals.
- B) Animals will be considered eligible for adoption when the PI signs the "Animal Adoption Record" indicating that the animal is no longer needed on the protocol. The adoption will proceed after a Wright State University veterinarian examines the animal and signs the adoption form, indicating that the animal's health status is appropriate for the adoption.
- C) Individuals adopting animals should:
 - 1) agree not to sell or give away the animal (except as noted in "F" below).
 - 2) agree to care for the animal in a manner generally accepted as appropriate for a pet of the species.
 - 3) agree with LAR's assessment of the animal's health.
 - 4) agree to not hold Wright State University liable for actions or circumstances arising from the adoption.
- D) Dogs and cats over four (4) months of age shall be neutered prior to release.
- E) Though a nominal charge may be assessed for neutering a prospective pet, there will be no fee charged for adoption.
- F) A recognized humane organization can adopt multiple animals through a cooperative arrangement and may pursue allowing the adoption of these animals to other individuals as stipulated in "C" above.

Animal Adoption Record
Laboratory Animal Resources, Wright State University

Species:		Breed or Type:		AUP transferred from:	
Identifying Marks/ Tattoo number/ Color:					
Sex:		Age:		Weight:	
Vaccination History of Animal (if applicable):					
Medical/Behavioral Information:					

Signature of LAR Veterinarian _____ Date _____

Signature of Principal Investigator _____ Date _____

1. I accept the adoption of the animal described above from The Laboratory Animal Resources of Wright State University (LAR). I agree with LAR's assessment that the animal is in good health. I do understand, however, that there are no expressed or implied guarantees relative to the health or temperament of the animal.
2. I accept responsibility for the care of the animal described above and will make all reasonable attempts to care for this animal in a manner that is generally considered appropriate for a pet of this species.
3. The animal described above is to be a pet for me and my immediate family. I understand that it is not to be sold, given away, or otherwise released from my care unless extreme circumstances require the same. If the animal described above must be released from my care, I will make every attempt to secure a satisfactory home environment for it.
4. I assume responsibility and agree to hold harmless from liability Laboratory Animal Resources and Wright State University or its agents, for any claim that may arise from the adoption of the animal described above.
5. I have read and understand the foregoing and voluntarily sign this Animal Adoption Record with full knowledge of its significance.

Name (Print) _____ Telephone _____

Address _____

Signature _____ Date _____

(Approved 12/14/2016)

COMPARISON OF ANIMAL USE PROTOCOLS AND PHS FUNDING REQUESTS (PROPOSALS)

For research that is supported by PHS funding, Principal Investigators will be required to compare the protocol submitted to the IACUC with the information submitted to the sponsoring agency or agencies in the relevant grant application. If the IACUC requires changes to the protocol that are not reflected in the grant application, then the PHS funding component must be notified in the follow-up certification of IACUC approval.

CONDUCTING IACUC BUSINESS IN THE EVENT OF A PANDEMIC OR OTHER SIGNIFICANT EMERGENCY

BACKGROUND

Planning for emergencies such as pandemic events is required by the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals ([Policy](#)). There are flexibilities provided in the PHS Policy that are applicable to implementing a pandemic plan for animal care and use programs. The PHS Policy also contains provisions that can be instituted as social distancing measures to prevent the spread of disease while conducting IACUC business. OLAW Notice Number: NOT-OD-20-088, [Flexibilities for Assured Institutions for Activities of Institutional Animal Care and Use Committees \(IACUCs\) Due to COVID-19](#), was released to guide Institutions specifically during the COVID-19 pandemic.

Wright State University's IACUC may implement the following measures during a pandemic or other significant emergency, as designated by the University Provost or applicable subcommittee, in order to ensure continuity of IACUC operations.

IACUC Members

- IACUC members and alternates will be appointed as necessary to maintain a properly constituted committee.
- New IACUC members will be appointed using previously described methods.
- New IACUC members will undergo all required training, using in person or videoconferencing methods as appropriate to the emergency situation.

IACUC Meetings

- The IACUC may conduct IACUC meetings via teleconference or videoconference, as approved in the WSU IACUC policy "Use of Telecommunications for Conducting IACUC Business" and according to OLAW Notice Number: NOT-OD-06-052.
- The number of IACUC meetings may be reduced to as few as one every six months.
- Any animal use protocol, amendment, or annual report may be reviewed using the designated member review method in lieu of full committee review, provided that all procedural review requirements of the Public Health Services (PHS) Policy and/or Animal Welfare Regulations (AWRs) are followed.
- IACUC meetings conducted via teleconference or videoconference are considered functionally equivalent to physically-convened meetings in which a quorum is required.
- A convened meeting with a quorum present must conduct the following:
 - Suspension of a protocol
 - Full committee review of protocols

Semiannual Facility Inspections

The IACUC may consider the following flexibilities in the conduct of semiannual animal facility inspections:

- The timing of facility inspections may extend 30 days beyond the six-month interval from the last review if there is no forward drift of the date from year to year.
- The IACUC has discretion to determine the best means of conducting the facility inspections. This includes using any qualified individual as *ad hoc* consultants.
- For areas housing non-USDA regulated species, the IACUC may use as few as one qualified individual to conduct the inspections, while areas housing USDA regulated species for > 12 hours require inspection by at least 2 members of the IACUC.
- The semiannual report may be signed by IACUC members digitally or with scanned signatures and submitted to the IO electronically. The IO may approve/accept the report by electronic review.

OLAW Waivers

OLAW may temporarily waive specific IACUC functions in accordance with PHS Policy Section V.D. The decision to request a waiver from OLAW in accordance with NOT-OD-20-088 or other applicable notices will be made upon consultation with the Institutional Official (IO), IACUC Chair or designee, IACUC Coordinator or designee, and Attending Veterinarian, as available. Waivers may be requested by the IO, IACUC Chair, IACUC Coordinator, or Attending Veterinarian by submission of the request for the function or functions to be waived, including justification to olawdpe@mail.nih.gov.

REFERENCES:

1. Institute for Laboratory Animal Research. 2011. Guide for the care and use of laboratory animals, 8th ed. Washington (DC): National Academies Press.
2. Animal Welfare Act and Regulations. 2017. United States Department of Agriculture.
3. Flexibilities for Assured Institutions for Activities of Institutional Animal Care and Use Committees (IACUCs) Due to COVID-19; Notice Number: NOT-OD-20-088; Release Date: March 16, 2020; Issued by: Office of The Director, National Institutes of Health ([OD](#)).
4. Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals; Notice Number: NOT-OD-06-052; Release Date: March 24, 2006; issued by: Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research (<http://grants.nih.gov/grants/olaw/olaw.htm>).

DISPOSITION POLICY

The university is committed to minimizing the number of animals needed to satisfactorily conduct its research, teaching, and testing activities while being in full compliance with applicable federal, state, and local regulations. The policy that follows indicates methods for the disposition of animals not requiring euthanasia and for the disposal of the remains of those which do.

1. Animals which are in excess of the number authorized or required for animal use protocols as well as animals that are alive at the conclusion of animal use protocols will be disposed of by one of the following means:
 - a. Animals may be transferred to active animal use protocols which contain requirements for the species in question. When not specifically approved in a protocol (i.e., either at original review or by amendment), transfer of animals from one approved protocol to another at Wright State will be done on a case-by-case basis.
 - b. Animals may be transferred for approved activities to other appropriate federally licensed facilities.
 - c. If animals are in appropriate health, they may be adopted in accordance with Wright State University's "Policy for Adoption of a Companion Pet".
 - d. If animals cannot be utilized as described above, they will be euthanized as described in Laboratory Animal Resources Standard Operating Procedures.
2. Requests for the transfer or disposition of animals other than as indicated in Item 1 above will be considered by IACUC on a case-by-case basis.
3. Tissues or individual organs of euthanized animals not exposed to infectious agents or chemical contaminants may be used by other investigators.
4. Requests for the disposition of uncontaminated remains, tissues, or organs of euthanized animals other than as indicated in item 3 above will be considered by IACUC on a case-by-case basis.
5. All other remains will be disposed of in accordance with all State and Federal Regulations.

Euthanasia Certification Procedures

Investigators or their designate must be certified in the euthanasia method approved in the protocol. All personnel responsible for performing euthanasia procedures must demonstrate proficiency in the method being performed with a representative of the Laboratory Animal Resource staff. Investigators are responsible for assuring that all their personnel carrying out euthanasia are properly trained in the method approved in the protocol.

POST-APPROVAL MONITORING OF WSU'S ANIMAL CARE PROGRAM BY THE IACUC

Introduction

The Wright State University Institutional Animal Care and Use Committee (IACUC) is charged with oversight of all care and use of animals in the University's research, teaching, or testing programs. This includes Post-Approval Monitoring (PAM), the meaningful monitoring of the protocols that have been approved by the IACUC in order to ensure the integrity of biomedical research and collect evidence to that effect for reporting purposes. The PAM process may involve laboratory/site visits to observe animal procedures being performed, evaluation of record keeping, confirmation of proper personnel training, and discussions related to approved activities. The process is meant to facilitate dialogue and education between the IACUC and researchers.

IACUC has approved the following mechanisms to provide periodic monitoring for compliance with IACUC Policies and Procedures and LAR Program of Animal Care:

1. Inspections conducted at least once every six months (semi-annually) of all of the institution's animal facilities, in accordance with WSU's "Assurance of Compliance with PHS Policy on Humane Care and Use of Laboratory Animals".
2. Selection of animal use protocols for additional review by an IACUC semiannual inspection subcommittee. Protocols will be selected for PAM review and the Principal Investigator will be requested to provide additional information by completing the "Post-Approval Monitoring Form". The IACUC subcommittee will review the form and study sites during the semiannual inspection. The review may involve observation of experimental procedures or interviews with the investigator and relevant staff. Results of this process will be reported in the semiannual inspection report, and investigators will be promptly notified.
3. Random visits to animal use areas and animal holding areas for inspection and discussion with investigators /staff about the procedures and methods they use for comparison with approved protocols and programs.
4. Instruction of researchers and staff in "whistle blower" mechanisms and responsibilities.
5. Training certification through LAR with education of all those who handle or use animals.
6. IACUC may request investigators to meet with the committee to discuss the review of their protocols.
7. Periodic reminders of policy and updates in requirements.
8. Development of SOPs for animal handling and use.
9. Monthly inspection of non-LAR housing facilities by the LAR staff.

NATIONAL SCIENCE FAIR PROJECTS

The IACUC recognizes the validity of responsible animal use in the educational process. To support educational efforts at local schools, the IACUC will assist in obtaining research animals for students/schools in restricted cases. Students may order animals which are not covered by the Animal Welfare Act of 1985 and relevant amendments to the act, and are for the purpose of National Science Fair Projects through the Laboratory Animal Resources at Wright State University under certain conditions. These conditions include the following:

1. The school must have an active Scientific Review Committee (SRC) that has approved a protocol for the proposed animal use following the requirements of the International Science and Engineering Fair (ISEF).
2. The WSU IACUC will have the right to review the protocol and to inspect facilities associated with the animal use.

NEUTERING OF CATS AND DOGS USED IN LONG-TERM PROTOCOLS

Animals which are housed for prolonged periods and used in survival protocols merit unique consideration regarding their humane use and long-term health. One issue is whether neutering is a beneficial procedure for these animals. The IACUC is particularly concerned with respect to purpose-bred or, if approved under the “Requirements for Conditioned and Unconditioned Animals” policy, conditioned random-source cats and dogs. For these reasons the IACUC institutes the following policy:

If cats or dogs are used in long term (over one year) protocols in which neutering will have no adverse effect on the research results/animal use, the IACUC will:

1. Consult with and provide the PI with information concerning risks and benefits of neutering these species, and,
2. In conjunction with the PI determine whether these animals will be neutered.

If it is determined that the animals should be neutered, the protocol will be appropriately modified.

USE OF APPROPRIATE NOMENCLATURE WHEN IDENTIFYING RESEARCH ANIMALS

NIH guidelines require that some mechanism exist within funded institutions for informing investigators of the importance of using standardized nomenclature when identifying the animals they use in biomedical research. Accordingly, the purpose of this policy is to serve as the mechanism by which this information is relayed to all personnel involved in animal research at Wright State University.

International committees have developed rules for standardized nomenclature of inbred mice, outbred rodents and rabbits. These widely accepted conventions permit accurate description of the animals used in research. Wright State University investigators are encouraged to use standard nomenclature conventions (found in supplier catalogs or through LAR) to describe the genetic background of their experimental animals when placing animal orders, when recording scientific data, and in publications. For animals obtained from commercial vendors, the strain (inbred animals) or stock (outbred animals) is that found in the breeder's price list.

The LAR office may be contacted for assistance in providing standardized nomenclature for animals.

OVERAGES IN ANIMAL USAGE

The number of animals approved in a protocol is considered to be an approximate number. A total overrun of up to 10% of the originally approved numbers is allowed. Overruns beyond this 10% are allowed only with the approval of an amendment to the protocol.

STUDENTS IN COURSES THAT USE ANIMALS FOR TEACHING

Students enrolled in academic courses that use animals for teaching purposes are not required to be listed on the Animal Use Protocol for Teaching Activities. However, students enrolled in such courses must complete all training requirements as stipulated in the Training Program for Animal Use/Handling policy. The faculty instructor will provide LAR with a class list and will ensure that all training requirements have been met prior to course content involving animals. The class enrollment list and confirmation of training completion must be available for IACUC inspection.

PROPOSALS CONTAINING PROPRIETARY DRUGS

IACUC will review the use of non-specified drugs or other such agents provided the investigator documents that these agents are proprietary/confidential information and the company does not allow their identification.

Available safety data, however, must accompany any and all such requests.

REQUIREMENTS FOR CONDITIONED AND UNCONDITIONED ANIMALS

The use of healthy dogs and cats is considered essential for the conduct of scientifically valid research. The use of dogs and cats specifically bred and raised for research ("purpose-bred" animals either from Class A dealers or privately-owned research colonies) is preferable to ensure reliable research results. In specific cases the use of random source animals may be necessary due to behavioral, experimental, or other reasons. Sources for such dogs and cats include Class B dealers, donations from private owners, or research conducted through veterinary clinical trials. In accordance with recommendations found in the Institute for Laboratory Animal Research (ILAR) report *Scientific and Humane Issues in the Use of Random Source Dogs and Cats in Research* (2009), dogs and cats used in NIH funded research will not be purchased from Class B dealers. When justified by experimental design, conditioned random-source dogs and cats may be purchased from Class B suppliers that are either a) Fully Accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care, Int. (AAALAC), or b) annually site inspected and approved by Laboratory Animal Resources (LAR)*.

*Laboratory Animal Resources is not responsible for the expenses related to either the AAALAC accreditation or the LAR site inspection required to qualify a supplier. If an LAR site inspection is requested, the expenses will be borne by the supplier or principal investigator requesting the site inspection.

INTER-INSTITUTIONAL ACTIVITIES

Animal Research Activities Subcontracted to Other Institutions

In every case where research is proposed at WSU and at other institutions, the WSU IACUC should review a protocol that fully describes the activities that will be conducted at WSU. In addition, when WSU is subcontracting federal funds for animal research to other institutions, the WSU PI should also briefly describe all planned animal research activities to be conducted at the subcontracted site(s).

The WSU IACUC may rely on the approval of an external IACUC for the remote animal research, if the institution has an NIH/OLAW approved Animal Welfare Assurance. In most cases, the external IACUC (or equivalent animal research ethics committee) will be asked to assume full responsibility for the animal activities in its facilities including responsibility for ongoing protocol review and animal facility inspections. RSP will determine whether the external institution has an approved NIH/OLAW Animal Welfare Assurance. The WSU IACUC will request the external documents for initial and ongoing IACUC approvals relative to the protocol.

Unaffiliated Personnel Conducting Animal Research in WSU Facilities

At times, it may be appropriate for persons who are not WSU employees or students to conduct animal research activities in University facilities. In these cases, the WSU IACUC must prospectively review and approve the proposed research. The IACUC will ensure that the non-affiliates are qualified to perform the research and have met the relevant standards of the WSU Training Program for Animal Use/Handling.

Unaffiliated Persons – Limited Participation in WSU Instructional Protocols

Sometimes persons who are not affiliated with the University briefly serve as guests demonstrators on instructional animal care and use protocols. In this case, the principal investigator must provide the IACUC with a list of credentials a person must have before the start of the course each time the course is offered.

The WSU faculty member directing the course will be responsible for the overall course activity. These guests may be exempted from mandatory trainings and from participation in the WSU Training Program for Animal Use/Handling.

WSU Personnel Conducting Animal Research at External Facilities

When WSU researchers engage in animal research activities at non-WSU locations, the WSU IACUC must prospectively review the entire research project. This does not include training and consulting activities conducted at other institutions or private facilities or work conducted on a protocol approved by another institution's IACUC. A copy of the local IACUC (or research ethics review committee) approval for the remote activities and a letter from the appropriate official at the collaborating institution authorizing WSU personnel to work at that location will be requested.

TERMINAL SURGERY: CLARIFICATION AS A PAINFUL/NON-PAINFUL PROCEDURE

(Memo from USDA)

“Some confusion has become apparent dealing with terminal surgery procedures. That animals used in terminal surgery procedures do not experience pain has apparently been misinterpreted to mean that terminal surgery with anesthesia is not a painful procedure and, therefore, does not require a search for alternative procedures by the investigator.

“To clarify the status of terminal surgeries under the Animal Welfare Act (AWA), it is the Department’s [i.e., USDA’s] position that terminal surgery is a potentially painful procedure with the pain alleviated by anesthesia (depending on the plane of anesthesia), and that it is to be considered a painful procedure which is alleviated by drugs. As a painful procedure, it requires that the investigator consider alternatives to the procedure and that the IACUC review and approve the procedure. If you have any research facilities that consider terminal surgeries to be non-painful procedures, they should be advised of this decision.”

Per this policy, protocols involving terminal surgery procedures will be classified as Category D under USDA, Pain and Distress Classification System.

THREE (3) YEAR REVIEW POLICY

Each Animal-use protocol shall be unique and shall be active for a maximum period of three (3) years.

At the end of its three (3) year expiration date, it shall be automatically inactivated and all animal activities covered under it shall be considered complete.

Ongoing or additional animal activities as may be required by the specific protocol must be submitted as a new animal use protocol which will be assigned a new AUP number.

AUP numbers shall be unique and not reused.

TRAINING PROGRAM FOR ANIMAL USE/HANDLING

It is the investigators' responsibility to ensure completion of all training for personnel on an Animal Use Protocol. The training program is divided into three (3) components as outlined below:

1. The introductory component (Introductory Course in Institutional Animal Care and Use) is comprehensive in scope and design and will provide a general background in the routine care, handling, and treatment of laboratory animals. This section will also provide a synopsis of the various regulations which control these activities. All individuals who will be involved with laboratory animals in handling, care or use, or for any other purpose, must complete this unit. This training may be obtained online as a "self-register" course available through www.pilot.wright.edu, and successful completion of the associated quiz is required. Presentation of the introductory component training in a lecture format may also be requested by contacting lar@wright.edu.
2. All individuals will also be required to complete the online Occupational Safety program and participate in the Occupational Health program for animal users.
3. Additional training is required of all investigators, staff, and students at least every 3 years. This training is considered "refresher training" and is available online or in person as a "self-register" course available through www.pilot.wright.edu. Successful completion of the associated quiz is required if the course is taken online.
4. Species-specific and/or procedure-specific training will provide additional instruction to investigators and technicians in animal care, handling, and treatment (e.g., various surgical procedures and techniques). Species-specific training is provided by www.citiprogram.org and is required prior to use of each species by research personnel. Comparable species-specific training taken by research personnel in the past (such as through www.aalaslearninglibrary.org) will be individually evaluated as a substitute. Procedure-specific training may be provided by LAR staff, or appropriately qualified and experienced research staff.
5. The qualifications of personnel conducting specific procedures in animals will be ensured through IACUC review of training and qualification at the time of the animal use protocol review. In cases where personnel qualification is difficult to determine, LAR staff may be requested to observe such procedures and confirm qualifications to the IACUC prior to unsupervised animal-use activities.

All investigators new to the university will be required to complete the mandatory sessions before being permitted to carry out any type of research.

Contact LAR (x2792) for complete details including web-address and institutional password.

TRAINING PROGRAM FOR IACUC MEMBERS

IACUC voting members, including alternates, are provided suitable orientation, appropriate materials, and adequate resources and training to enable them to carry out their duties consistent with the *Guide for the Care and Use of Laboratory Animals*, the PHS Policy, and the Animal Welfare Regulations.

1. Initial training may be provided by the attending veterinarian, IACUC Chair, and IACUC staff. Topics include the following:
 - a. IACUC history, evolution, and regulatory entities.
 - b. IACUC roles, responsibilities, and relationships within the institution, federal oversight, and funding agency involvement.
 - c. Institutionally specific operation and procedures to include protocol submission, review, amendments, semiannual facility and program reviews, handling animal welfare concerns, and post approval monitoring methods.
2. Additional online training through www.citiprogram.org is required, including the following course: *Working with the IACUC: Investigators, Staff, and Students*. A more detailed course, *IACUC Chairs, Members and Coordinators*, is also available and may be taken optionally.
3. Occupational Safety training for indirect contact with laboratory animals (Awareness Training) is also required, and may be accessed through www.citiprogram.org.
4. All IACUC voting members are required to participate in the Occupational Health program. The Medical Surveillance form must be completed for review by the occupational health physician. Additional involvement in the occupational health program is at the discretion of the occupational health physician.
5. IACUC voting members will provide an updated curriculum vitae to the IACUC coordinator to confirm they are qualified to serve in the specific role for which they are assigned.
6. Upon completion of training, IACUC voting members will be asked to confirm in writing whether they agree that animal use protocol clarifications may be reviewed using the designated member review procedure after initial review by the full committee.

USE OF NON-PHARMACEUTICAL GRADE DRUGS

BACKGROUND

OLAW and USDA consider that the use of any non-pharmaceutical grade (non-USP*) compound should be based on scientific necessity, no availability of an acceptable veterinary or human pharmaceutical-grade compound, and specific review and approval by the IACUC.^{1, 2}

DEFINITIONS

1. Pharmaceutical grade compound: Drug, biologic, reagent, etc. which is approved by the FDA or for which a chemical purity standard has been written/established by USP/NF, BP.
2. Analytical grade bulk chemical: ~99% purity; Certificate of Analysis is usually available
3. Non-availability: Not commercially available from an active US vendor; includes formulations supplied as tablet, capsule, injectable, etc.
4. New investigational compound: Supplied by its manufacturer for testing in an experimental setting only and for this reason would not have chemical purity standards established; by default is considered a non-pharmaceutical grade compound
5. USP/NF: United States Pharmacopeia/National Formulary. The United States Pharmacopeia (USP) is an official public standards-setting authority for all prescription and over-the-counter medicines.
6. BP: British Pharmacopeia
7. FDA: Food and Drug Administration; FDA approved compounds are manufactured using USP/NF compounds

PRINCIPLE

The use of pharmaceutical-grade compounds in laboratory animals ensures that the compounds administered meet established documentable standards of purity and composition which in turn help ensure research animal health and welfare, as well as the validity of experimental results. The use of lower grade chemicals/compounds with higher levels of impurities or poorly formulated non-commercial preparations can introduce unwanted experimental variables or even toxic effects, and so should be avoided if at all possible. Although pharmaceutical grade compounds should be used in experimental animals whenever possible, the use of non-pharmaceutical-grade compounds in experimental animals is an acceptable practice under certain circumstances. For example, in the case of new investigational compounds, they would be the only grade and formulation available.

The NIH Office of Laboratory Animal Welfare (OLAW) and the United States Department of Agriculture (USDA) both have determined that the use of non-pharmaceutical-grade compounds should be based on (1) scientific necessity, (2) non-availability of an acceptable veterinary or human pharmaceutical-grade compound, and (3) specific review and approval by the IACUC. Cost savings alone is not considered an adequate justification for the use of non-pharmaceutical-grade compounds in laboratory animals.

OLAW has also stated that while the possible implications of the use of non-pharmaceutical grade compounds in non-survival studies appears less evident, the scientific issues remain the same and professional judgment, as outlined above, must still apply. It is important to understand that this guideline pertains to all components, both active and inactive, contained in the preparation to be administered. Therefore, the vehicle used to facilitate administration of a compound is as important of a consideration as the active compound in the preparation.

¹ PHS Policy on Humane Care and Use of Laboratory Animals, Frequently Asked Questions: May investigators use non-pharmaceutical grade compounds in animals? (updated: 11/19-2012)

² United States Department of Agriculture, Animal and Plant Inspection Service, Veterinary Medicine, Animal Care: Animal Care Resource Guide, Policy #3

Institutional Animal Care and Use Committee Policy

Pharmaceutical Grade Compounds must be used, when available, for all animal-related procedures.

When selecting compounds the following order of choice should be applied:

1. FDA approved veterinary or human pharmaceutical compounds
2. FDA approved veterinary or human pharmaceutical compounds used to compound a needed dosage form
3. USP/NF or BP pharmaceutical grade compound used in a needed dosage form
4. Analytical grade bulk chemical used to compound a needed dosage form (requires justification)
5. Other grades and sources of compounds (requires justification)

NOTE: For new investigational drugs the grade and formulation is not optional, but the investigator and IACUC can verify health and safety issues described below.

Non-pharmaceutical-grade compounds can only be used in research activities utilizing animals if reviewed and approved by the IACUC. The following circumstances must be met for consideration by the IACUC:

1. The research activity requires the use of non-pharmaceutical-grade compounds for reason of scientific necessity.
2. Acceptable veterinary or human pharmaceutical-grade products are not available (most novel compounds are in this category).
3. Cost savings alone is not an adequate justification for using non-pharmaceutical-grade compounds in animals.
4. For all species, any non-pharmaceutical chemical agents administered parenterally (by injection) must be sterile, maintained in a sterile container, and labeled to provide the mixing date, name and concentration of all components.

Guidelines for Non-Pharmaceutical Grade Compound Use:

When developing and reviewing a proposal to use non-pharmaceutical grade compounds, the PI and IACUC should consider animal welfare and scientific issues related to the use of the compounds, including potential for contamination, safety, efficacy, and the inadvertent introduction of confounding research variables.

For all compound use, the IACUC should consider the grade/purity being proposed, the formulation of the final product, and issues such as sterility, pyrogenicity, stability, pH, osmolality, site/route of administration, pharmacokinetics, physiological compatibility, and quality control.

Recommendations for Protocol Applications:

Protocols should include the following information when a non-pharmaceutical grade product is utilized:

- Chemical grade of compound (see definitions above)
- Source
- Formulation and vehicle for compound
- Preparation of compound (if applicable)

Pentobarbital

Pentobarbital is a commonly used anesthetic. The recent exorbitant cost increases of the only commercially-prepared pentobarbital solution, Nembutal®, have placed it logistically into the unavailable category.³

³ Use of Non-Pharmaceutical-Grade Chemicals and Other Substances in Research with Animals. Transcript from Office of Laboratory Animal Welfare Online Seminars. March 1, 2012

Alternatively, pentobarbital is available through compounding pharmacies at a lower price than Nembutal. The use of compounded pentobarbital for anesthesia is considered acceptable. All other forms of pentobarbital must be approved on a case-by-case basis by the WSU IACUC.

OLAW in concert with USDA agree that a procedure may be performed as a part of euthanasia. And this would be limited to terminal perfusion or exsanguination. In both cases, death is an immediate outcome of the procedure.³ Therefore, euthanasia solution may be used for terminal perfusion or exsanguination procedures.

PHYSICAL RESTRAINT

Physical restraint is defined as the use of manual or mechanical means to limit some or all of an animal's normal movement for the purpose of examination, collection of samples, drug administration, therapy, or experimental procedures.⁴ Physical restraint may be stressful, distressful, or painful if performed inappropriately. The animal's welfare is impacted by choice of restraint device, acclimation procedures, and experimental procedures performed during restraint. Complete immobilization of an animal is highly stressful and may only be used when essential to research objectives.

Holding an animal for a few moments by hand or in a restraint device is not considered physical restraint. Animals that are sedated or anesthetized to limit movements during procedures are not considered physically restrained.

The following are guidelines for physical restraint of any duration:

1. Restraint devices should not be considered a normal method of housing, and must be justified and fully described in the animal use protocol.
2. Restraint devices should not be used simply as a convenience in handling or managing animals.
3. Restraint devices should be suitable in size, design, and operation to minimize discomfort or injury to the animal. Less restrictive systems should be used when compatible with research objectives.
4. Alternatives to physical restraint should be considered.
5. The period of restraint should be the minimum required to accomplish the research objectives.
6. Animals to be placed in restraint devices should be given training with positive reinforcement to adapt to the equipment and personnel. Prolonged restraint of a non-acclimated animal may only be used if essential to research objectives (e.g. when restraint is used as a stressor).
7. Unless restraint is approved as a stressor, animals that fail to adapt should be removed from the study.
8. Provision should be made for observation of the animal at appropriate intervals.
9. Restraint devices must be cleaned after each use and sanitized regularly.

⁴ The Guide for the Care and Use of Laboratory Animals – 8th edition (National Research Council, 2011)

USE OF TELECOMMUNICATIONS FOR CONDUCTING IACUC BUSINESS

BACKGROUND

Sections IV.C.2 and 6 of the PHS Policy require, respectively, that full committee approval of a proposed research project or suspension of an activity by the IACUC occur only after review of the matter at a convened meeting of a quorum of the IACUC and with the approval or suspension vote of a majority of the quorum present. In 2006, OLAW issued Notice Number NOT-OD-06-052 clarifying the appropriate use of telecommunications for IACUC business. The United States Department of Agriculture issued identical provisions in its Animal Welfare Inspection Guide.

Alternate electronic methods meeting certain criteria may be considered functionally equivalent to physically-convened meetings in which a quorum is required. The traditional convened meeting physically attended by IACUC members provides the optimal forum in which to conduct full committee review of proposals and consider potential suspensions. Introduction and integration of new members to the Committee is also most effectively accomplished during physically-convened meetings. However, OLAW recognizes that some forms of telecommunications facilitate the conduct of business, reduce regulatory burden, are standard practice in many forums, and enhance flexibility without compromising the quality of deliberation and interaction.

POLICY

Video or teleconferencing allows for real time verbal interaction equivalent to that occurring in a physically-convened meeting (i.e., members can actively and equally participate and there is simultaneous communication). Video or teleconferencing is acceptable for the conduct of official Wright State University IACUC business requiring a quorum, provided the following criteria are met:

1. All members are given notice of the meeting.
2. Documents normally provided to members during a physically-convened meeting are provided to all members in advance of the meeting
3. All members have access to the documents and the technology necessary to fully participate in real time IACUC deliberations.
4. A quorum of voting members is convened when required by PHS Policy. A quorum includes members on the video conference.
5. If a vote is called for, the vote occurs during the meeting and is taken in a manner that ensures an accurate count of the vote.
6. Written minutes of the meeting are maintained in accord with PHS Policy, IV.E.1.b.
7. Remote meeting sites must be private and only those authorized to participate in an IACUC meeting may be in attendance at the remote site.

Video conferencing may be used for conducting semi-annual inspections at Wright State University's Lake Campus. The Principal Investigator or a member of his/her laboratory or department will be on location with the technology that allows real time viewing of the laboratory space. An IACUC subcommittee of at least 2 members must also be available to participate in the video conference. The following criteria must be met for inspections with video conferencing to take place:

1. The Lake Campus facility must not be approved as a housing or study site for “animals” as defined by the Animal Welfare Act.
2. No live animals will be housed at Lake Campus at the time of the inspection.
3. At least one in-person inspection will be conducted at Lake Campus per year.

REFERENCES:

1. Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals; Notice Number: NOT-OD-06-052; Release Date: March 24, 2006; issued by: Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research (<http://grants.nih.gov/grants/olaw/olaw.htm>).
2. United States Department of Agriculture, Animal Welfare Inspection Guide, Chapter 7.9. 2013. https://www.aphis.usda.gov/animal_welfare/downloads/Animal-Care-Inspection-Guide.pdf

IACUC MEMBER CONFLICT OF INTEREST POLICY

Purpose

Federal regulations prohibit IACUC members from participating in the review or approval of IACUC activities in which that member has a conflict of interest. The purpose of this policy is to identify IACUC member conflicts of interest, ensure the objectivity of the research, and the welfare of animals used in research.

Definitions

Conflict of Interest - A financial interest or other opportunity for tangible personal benefit of an individual or his/her immediate family that may exert a substantial and improper influence on the individual's professional judgment in exercising any University duty or responsibility, including the review of research. Note: For IACUC members, financial and non-financial interests/opportunities are included.

Financial Conflict of Interest - An interest of an individual (or his/her immediate family) of monetary value that would reasonably appear to be affected by the research or an individual's interest in any entity whose financial interests would reasonably appear to be affected by the research. Note: Financial interests include (but are not limited to) salary or other payments for services (e.g., consulting fees or honoraria), equity interests (e.g., stocks, stock options, or other ownership interests), and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

Non-Financial Conflict of Interest - An interest other than monetary of an individual (or his/her immediate family) in the design, conduct, or reporting of the research or other interest that competes with an IACUC member's obligation to protect animals and potentially compromises the objectivity and credibility of the research review process.

Immediate Family - For purpose of this policy, an IACUC member's spouse or domestic partner and dependent children.

Responsibility

The parties responsible for implementing this policy and procedure include the following: Office of the Vice Provost for Research and Innovation (ORI) staff, IACUC Chair, IACUC Members, and IACUC Consultants.

Procedures

1. No IACUC member may participate in the review of any research project, including study updates and submissions, in which the member has a conflict of interest, except to provide information as requested.
2. It is the responsibility of each member of the IACUC to disclose any conflict of interest prior to conducting a review and to excuse themselves from deliberations and voting.
3. ORI staff will document all conflict of interest disclosures in the IACUC meeting minutes.
4. Violations of this policy will be resolved by agreement between the IACUC Chair and Vice Provost for Research and consistent with applicable rules, regulations, and university policies.

Additional Information

Animal Welfare Act ("AWA"), Public Law 89-544, 7 U.S.C.)

Office of Laboratory Animal Welfare (OLAW) IACUC Guidebook, 2nd Ed. 2002

[Wright State University Policy 6110](#)

ENDPOINTS IN ANIMAL RESEARCH

The Public Health Service Policy and Animal Welfare Regulations require IACUCs to ensure that animal discomfort is limited to that which is unavoidable for the conduct of scientifically valuable research. The principal investigator should consider the impact of experimental procedures upon the animal's well-being and should identify, explain and include in the protocol a study endpoint that is both humane and scientifically sound. Even if pain or distress are not anticipated, every protocol should contain a contingency plan for dealing with unexpected situations that may arise.

Experimental Endpoints

These occur when the scientific aims and objectives of an experimental study have been reached and the study is concluded. Ideally, experimental endpoints are reached prior to humane endpoints.

Humane Endpoints

Humane endpoints refer to one or more predetermined physiological or behavioral signs that define the point at which an experimental animal's pain and/or distress is terminated, minimized or reduced by taking actions such as euthanizing the animal, terminating a painful procedure, or giving treatment to relieve pain and/or distress. Humane endpoints are considered a refinement as they provide an alternative to experimental endpoints, therefore reducing the animal's pain and/or distress that might be experienced. Humane endpoints should be chosen that are objective and relevant for the species and experimental procedures.

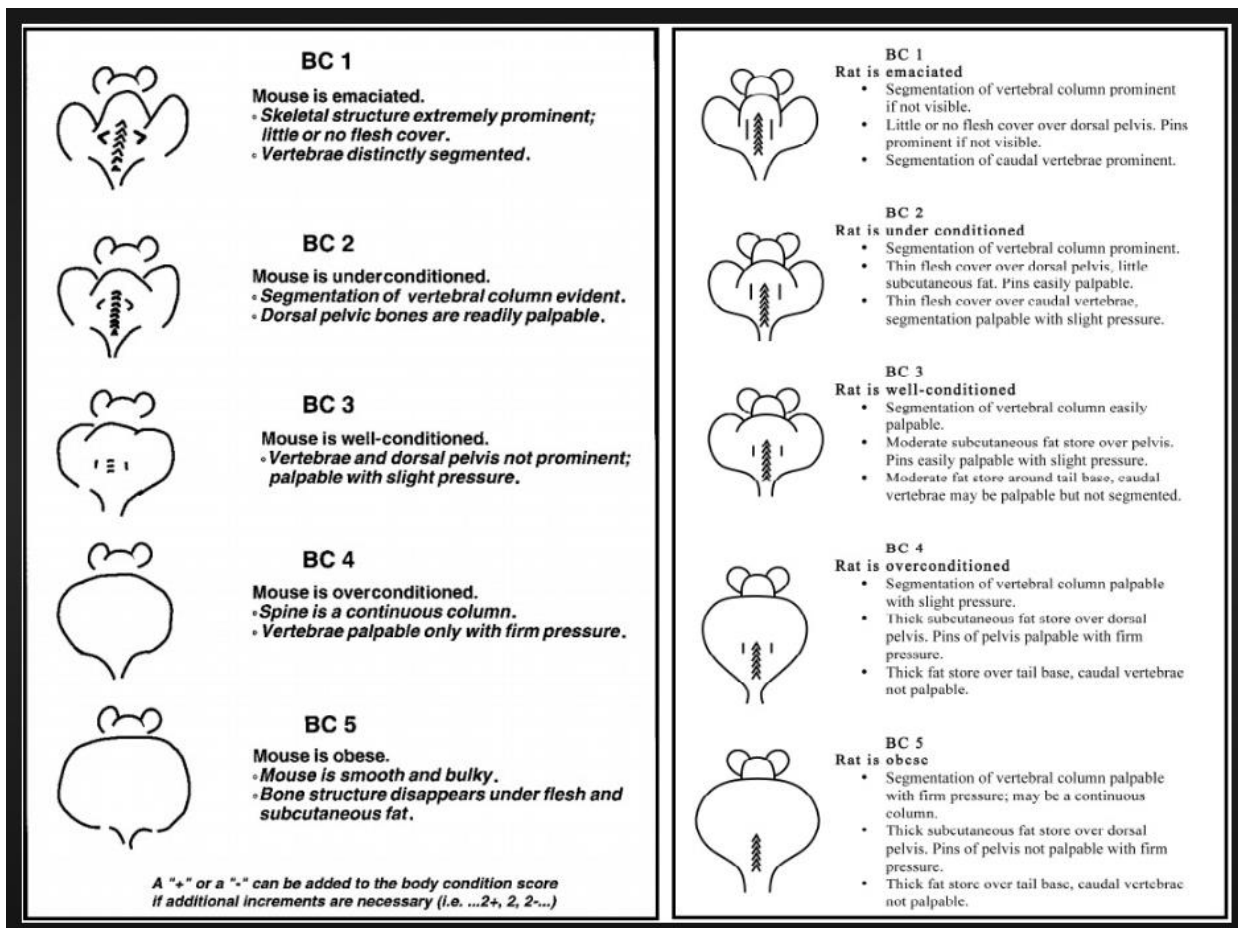
Research personnel responsible for observing and evaluating animals must be adequately trained and experienced in the recognition of these signs for the species being used. Especially when using behavioral assessment, personnel must be familiar with "normal" before they can be expected to recognize "abnormal". Investigators are responsible for ensuring these students and employees are appropriately trained.

Non-specific signs of illness such as weight loss, lethargy, hunched posture or a rough coat are an indication that an animal should be examined more closely. The following humane endpoints are recommended for all animals, unless the presence of such symptoms is scientifically justified in the Animal Use Protocol and approved by the IACUC:

- Weight loss > 15-20%. Growing animals should be compared with age matched controls. Alternatively, body condition (BC) score of 2 may be used as an endpoint (see below).
- Labored breathing
- Inability to rise or ambulate
- Inability to access food and water, or refusal of food and water.
- Unexpected abnormalities likely to cause pain or distress

Body Condition Scoring For Rats and Mice

This method can be a sensitive objective assessment of weight loss in animal models where organ enlargement, ascites, or tumor development may mask weight loss.^{3,4}



Specific Endpoints

In addition to those previously mentioned, endpoints should be developed specific to the experimental procedures animals will undergo when possible. The following endpoints should be considered mandatory criteria for euthanasia in rodents unless specifically excluded by an approved protocol.

Tumor Studies

- Tumor burden exceeding 10% of the animal's body weight. Tumor burden should always be limited to the minimum required for a valid scientific outcome. Tumor volume is a good indicator of size of the tumor burden. This can be calculated by $0.5 (L \times W \times D)$ with $1-1.5 \text{ cm}^3$ being the recommended endpoint.
- Tumor size in one dimension of $> 2 \text{ cm}$ for mice or $> 4 \text{ cm}$ for rats.
- Tumor ulceration, bleeding, or necrosis.
- Tumor interference with normal ambulation or eating.

Foot Pad Injections (or foot pad injury)

- The injected foot is inflamed or infected (evidenced by redness, swelling, and discharge) and the animal is unable to bear weight on that foot.
- The injected foot becomes ulcerated (excoriated skin, scabbing).
- The injected foot becomes necrotic - dark brown to black discoloration.
- The injected foot has been traumatized by self-mutilation.

Surgical Procedures

- Post-surgical pain or distress not amenable to treatment. Depending on the species, signs of pain or distress may include lethargy, self-mutilation, increased respiratory rate, vocalization, or others. Veterinary assistance should be obtained.
- Dehiscence, bleeding, or infection at the surgical site not amenable to treatment. Veterinary assistance should be obtained.

Death or Moribundity as an Endpoint

The term moribund refers to an animal that is near death or in the process of dying. Animals in this state are often comatose (unresponsive and unaware of stimuli) and so beyond awareness of suffering. However, an animal may have experienced much pain and distress prior to reaching a moribund state. Stating that animals will be euthanized when they become moribund is not an appropriate humane endpoint as this may not reduce or alleviate any suffering that the animal will experience. **It is Institutional Policy that any animal determined to be moribund in the opinion of the Veterinarian will be humanely euthanized. Any exception to this policy requires thorough explicit justification and prior IACUC approval.**

While certain types of studies have historically used death of the animal as a scientific endpoint, this is now rarely accepted and investigators must present conclusive evidence to support the use of such an endpoint.

The scientific rationale for death or moribundity as an endpoint must address:

- What alternatives were considered, why morbidity as an endpoint cannot be used, and how alternatives will be used whenever possible.
- The number of animals that will be allowed to reach moribundity/death and justification for it being the minimum necessary to achieve the scientific objectives.

References:

1. Foltz CH, Ullman-Cullere MH. 1999. Guidelines for assessing the health and condition of mice. *Lab Anim* 28:28–32 [[Google Scholar](#)]
2. Guidelines for Endpoints in Animal Study Proposals. 2019. https://oacu.oir.nih.gov/sites/default/files/uploads/armac-guidelines/b13_endpoints_guidelines_24apr2019.pdf
3. Ullman-Cullere, MH and CJ Foltz. 1999. Body condition scoring: A rapid and accurate method for assessing health status in mice. *Lab Anim Sci.* 49(3):319-323
4. Hickman DL, Swan M. 2010. Use of a Body Condition Score Technique to Assess Health Status in a Rat Model of Polycystic Kidney Disease. *JAALAS* 49(2):155-159.