

LACUC POLICIES AND PROCEDURES

AT

WRIGHT STATE UNIVERSITY

OCTOBER, 2007

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MISSION STATEMENT

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.

The Laboratory 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 Laboratory 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.

COMMITTEE STRUCTURE

GENERAL COMMITTEE STRUCTURE

Membership: Members are appointed by the President of Wright State University for a term of two years. 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.

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 Chair with concurrence of the Committee. The Vice-Chair is authorized to assign primary reviewers to new animal use petitions, chair LACUC 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. Attendance at the introductory training for investigators.
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 attorney, 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 may be included in the minutes of all meetings as well as the Semi-Annual Report.

ALTERNATE LACUC MEMBERS RESPONSIBILITIES

(05/03/07)

1. Alternates are appointed in the same manner (i.e., by the President) 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. LACUC Alternates and their Voting member may not contribute to a quorum at the same time or act in an official LACUC-member capacity at the same time (i.e., an Alternate may only contribute to a quorum and function as an LACUC member if the Voting member for whom they serve as alternate is unavailable).
4. Alternate members are, however, encouraged to attend LACUC meetings and participate in all other LACUC activities (e.g., review of protocols and/or amendments, discussion of protocols, and serve on subcommittees for inspections & investigations of non-compliance) provided a conflict in voting responsibilities does not occur between Alternate and Voting members.

PROCEDURES

GENERAL LACUC REVIEW/APPROVAL PROCEDURES

1. Electronic Submissions and Notifications
 - a. To the extent possible, all Committee business will be conducted electronically through the LACUC home page designated WSU's "Laboratory Animal Care and Use Committee, Protocol Management System" at <<http://lacuc.wright.edu/>>. It is the future goal of the Committee to eventually provide the capability to conduct as much of its business as reasonably possible and acceptable via electronic means.
 - b. Prior to conducting any electronic business with the Committee, it will be necessary for first-time users to register on the web site. This one-time registration involves:
 - i. Accessing the web address above
 - ii. Following the 'prompt' for obtaining a username and password
 - iii. Supplying the information requested to "Create User Account"
 - c. Follow the 'prompts'/'links' that support your proposed action (e.g., "Forms" to submit amendment, submit continuing review, etc.).
 - d. The program provides on-line forms, has 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, provided the required hard copy, with original signature(s), is submitted to RSP within three (3) business days.
2. Designated Review
 - a. In rare instances involving petitions requiring rapid review, the LACUC Chair may, upon request from the PI, authorize processing the petition via the "Designated Reviewer" process.
 - b. Designated Review involves protocol review by a convened subcommittee of at least one LACUC member appointed by the Chair, following distribution of a full copy of the requested action and supplemental material to all LACUC members with allowance of sufficient time for them to request Full Committee review (e.g., three (3) working days).
 - c. If no member requests Full Committee review, then the requested action will be reviewed by subcommittee and the investigator will be notified of the results.

The Designated Review subcommittee may either approve the protocol, require modifications to secure approval of the protocol, or refer the protocol to the full LACUC for review. Subcommittee actions MUST be by consensus if the subcommittee is composed of more than one LACUC member.

- d. Such Designated Review shall be followed by notification of the outcome to the full Committee at the next LACUC meeting.
3. New and renewal protocol applications that are not reviewed by Designated Review are reviewed by Full Committee Review.
4. Protocols that have been approved pending receipt of clarifications not involving major changes may be approved by the Chair plus one other LACUC member (usually the Veterinarian) with notification of the LACUC. Clarifications involving major changes are returned to the full committee. The LACUC determines whether a clarification should come back to the committee at the time it grants approval pending clarification to the protocol.

Regardless of the nature of the requested changes (i.e., 'non-major' or 'major'), such requested clarifications, responses to restrictions, or other requested changes, shall be incorporated into a revised protocol with the revision(s) highlighted.

5. Annual (Continuing) Reviews are conducted by two committee members (one of which should be the Veterinarian) with notification of the LACUC unless full Committee review is requested by a reviewer, a LACUC member, or is mandated by other such policy. All LACUC members are provided with a listing of protocols due for Annual (Continuing) Review during the next 60 days at each monthly convened meeting.
6. Amendments (either alone or as part of an annual review) involving significant changes are reviewed by the full committee. Amendments (either alone or as part of an annual review) involving non-significant changes may be approved by two (2) committee members, usually the Chair and the Veterinarian, with notification of the LACUC. Either reviewer may decide that an amendment is significant and requires full LACUC review.

Generally, amendments to animal protocols are presumed to be Significant with the following exceptions:

- a. deletion of personnel from protocols (this may also be treated as “Information”)
 - b. addition of personnel with written assurances from the principal investigator that the new personnel will not be conducting invasive procedures in living animals (e.g., euthanasia, injections, surgery, tattooing, etc.) or that the person being added is already trained and approved to perform the procedures under a different active approved animal use protocol.
 - c. a nonsignificant change in administrative matters (e.g., department change) and/or the request for additional (less than 10% of original approval) animals
7. Closures of protocols are carried out by Research and Sponsored Programs (RSP) with notification to LACUC.

8. Certifications of Current Protocol Approval are carried out by Research and Sponsored Programs (RSP) with notification to LACUC.
9. The transfer of animals from one approved protocol to another approved protocol will be done on a case-by-case basis unless approved by the LACUC as part of the approved protocol (i.e., either at original review or by amendment).

PROCESSING ANIMAL USE PROTOCOLS AND AMENDMENTS

New Protocols

I. Veterinarian Screening:

Prior to submission to Research and Sponsored Programs (RSP), protocols must be screened by the LAR Director/Veterinarian for animal care and treatment issues.

Outcomes of this screening may be:

- A) **The Veterinarian Endorses:** The Veterinarian will sign the protocol and it may be forwarded to the office of Research and Sponsored Programs (RSP) (Section II of this procedure).
- B) **The Veterinarian does not endorse and/or suggests the PI rewrite the protocol:** The Veterinarian will notify the PI as to how the protocol should be modified. A modified protocol may then be presented to the Veterinarian.
 - 1) If the Veterinarian concurs with the modified protocol he/she will sign the new protocol or the additional information and the protocol may then be forwarded to RSP.
 - 2) If the Veterinarian does not concur with the modified protocol he/she will proceed as in Section I.B.
- C) The PI may insist that a protocol be accepted by RSP without the Veterinarian's approval by submitting the protocol with a statement regarding his/her reasons for disagreeing with the Veterinarian's opinion to RSP (Section II of this procedure). Under these circumstances, the Veterinarian must indicate that the PI consulted with them concerning pain and distress issues during protocol development.

II. Protocol Receipt and Initial Processing

A protocol, either: a) reviewed and endorsed by the university Veterinarian or, b) reviewed but not endorsed by the Veterinarian accompanied by a statement from the PI justifying his/her disagreement with the Veterinarian's opinion, may be forwarded to RSP (electronically if available or in hard copies per instructions on the petition). The petition will be:

- A) Date stamped.
- B) Assigned a protocol number.
- C) Filed (Original Copy) as the official record.
- D) If the petition qualifies for Designated Review, the review procedure will be as previously described.
- E) If full Committee review is warranted, the procedure will be:
 - 1) The LACUC chair will assign a primary reviewer.
 - 2) Copies of the protocol will be distributed to LACUC members.

III. LACUC Review:

New protocol review by full Committee will be conducted as below:

- A) LACUC members will screen the protocol and communicate any concerns to the primary reviewer.
- B) The primary reviewer may act as a liaison between the LACUC members and the PI to address questions/concerns of committee members
- C) At the next LACUC meeting the primary reviewer will give the Committee a short synopsis of the protocol and the protocol will be discussed.
- D) The committee will vote to: approve, approve pending modifications/clarifications, defer action (usually pending further information and/or clarification), or withhold approval of the protocol. In general, approval pending modification/clarification will be given if the committee considers the clarification is sufficiently minor or straightforward so that the Chair and Veterinarian can certify the modifications/clarifications are adequate.

IV. Outcomes of LACUC Actions (similar regardless of review by Designated Review or full Committee review):

- A) If the protocol is approved:
 - 1) The LACUC chair will sign a notice of approval and forward it to the Institutional Official for full approval.
 - 2) A copy of the signed notice of approval and the protocol will be sent to LAR.
 - 3) A copy of the approval and a letter will be sent to the PI indicating that animals may be ordered and research covered by the protocol begun.
- B) If the protocol is approved pending modification/clarification:
 - 1) A request for modifications/clarifications will be sent to the PI and he/she will be asked to respond by a prescribed time. A protocol will be considered withdrawn if a timely response is not received.
 - 2) Upon receipt of the modifications/clarifications, the Chair plus one other LACUC member (preferably the Veterinarian) will review the response and either certify that it is adequate and proceed as in Section IV.A. or bring the response to the full committee as in Section III., as appropriate (See Section IV.E.)
- C) If the protocol 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 by a prescribed time. A protocol will be considered withdrawn if a timely response is not received.
 - 2) Upon receipt of the PI's response to RSP, RSP will proceed either by Designated Review as previously described, or as in Section III., as appropriate (See Section IV. E.)
- D) If approval withheld (outcome possible only following full LACUC review):
 - 1) The PI will be notified of the action and the reasons for the action.
 - 2) Although PI's will be given the opportunity to respond to this action, in general, if approval 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. (Review Outcomes), 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.

Amendments to Active Protocols

I. Amendment Receipt and Initial Processing:

Amendments will be received either electronically or as hard copy by RSP. If Designated Review is allowed, the review procedure will be as previously described.

If by full Committee review, the procedure will be as follows:

- A) The amendment will be date stamped.
- B) Copied for the protocol file.
- C) A determination of “Significant” vs. “Nonsignificant” will be made either administratively (by RSP) or by a preliminary Screener (usually the Veterinarian).

(For further information concerning “Significant” and “Nonsignificant” amendments, see Item #6 under “General LACUC Review/Approval Procedures”.)

II. Screening:

- A) If the amendment qualifies as Nonsignificant, the amendment will be sent to preliminary and secondary Screeners. If both Screeners agree that the amendment is Nonsignificant and is acceptable as written, the Chair and Institutional Official will sign the action form and the PI will be notified that the amendment is approved and in force.
- B) If the amendment is Significant or found to be not acceptable as written, it will be processed as in Section III of the "Procedures for Reviewing New Protocols".
- C) Review outcomes are as described above for new protocols.
- D) The decision as to whether an amendment is handled as Nonsignificant or requires full Committee review is independent of whether that protocol is subject to full Committee continuing review requirements.

Annual (Continuing) Review of Protocols

I. Information for Continuing Review:

- A) At least two (2) months before the anniversary of a protocol, a continuing review questionnaire will be sent to the PI. The PI will be asked for a timely response.
- B) If a response is not obtained the protocol will be inactivated after appropriate warning.
- C) Each month, RSP will distribute a list of those protocols having continuing reviews coming due for that month and the following month to committee members for their information and comment (e.g., request for full Committee review).

II. Screening:

- A) See the Policy entitled Annual Review of Protocols by Full LACUC (below) for those protocols requiring automatic continuing review by the full Committee
- B) For other protocols eligible for Continuing Review, the following procedure will be followed:
 - 1. Once information is received it will be reviewed by a designated LACUC member (i.e., designated by the LACUC Chair) and the Veterinarian specifically for:
 - a) Changes in the protocol
 - b) Changes in regulations that require modification of the protocol.
 - 2. If there are no changes or only minor changes and if no Committee member requests full Committee review (e.g., from I.C. above) then the protocol will be handled as a minor (Nonsignificant) amendment would (Section II.A . of the procedures for reviewing “Amendments to Active Protocols”). This shall be continuing review by the Designated Reviewer method.
 - 3. If the Veterinarian, designated LACUC member, or any other Committee member (e.g., from B.1. above) believes the committee should review the continuing review information, the protocol will be handled as a Significant amendment would (Section II.B. of the procedures for reviewing “Amendments to Active Protocols”). This shall be continuing review by the Full Committee method.

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

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

FORMAT FOR SUBMITTING PROTOCOLS

Petitions to the LACUC regardless of source (e.g., internal or external users) must be made using the petition form currently approved by the LACUC. VA personnel may use the VAMC Animal-Use Protocol Format as currently approved but must include the WSU-LACUC face pages.

The following forms are currently approved by the LACUC and are available for downloading through Research and Sponsored Programs' (RSP) home page (at <http://www.wright.edu/rsp/>) for:

1. Research activities
2. Teaching activities
3. Amendments

In addition, the petition for amending a protocol is currently available through the LACUC home page at http://wright.edu/cgi-bin/lacuc/lacuc_public.cgi.

Call for renewal protocols will be initiated by RSP and shall utilize the same forms as are used for initial review.

Requests and appropriate information for Annual (Continuing) Reviews will be sent from RSP.

REPORTING THE MISTREATMENT OF ANIMALS AND DEFICIENCIES IN THEIR CARE 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 and 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 protocols.

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 Laboratory Animal Care and Use Committee (LACUC), any member of the LACUC, the Director of Laboratory Animal Resources (LAR) 937-775-2792, or the Institutional Official 937-775-3336. Contact telephone numbers for all these individuals are posted in animal facilities. Timely reporting is essential to protect the animals involved and to aid the investigation of the allegations.
 - 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. 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 person or persons alleged to be delinquent, 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 LACUC 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 Laboratory 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 Laboratory 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 protocols involved, or other disciplinary actions. Disciplinary action may be appealed through existing procedures.
5. This policy will be distributed to all personnel involved in any way in animal research at or through WSU facilities during annual investigator training sessions. Personnel attending these sessions will be required to sign a document indicating 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 instruction 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."

(Approved - 09-13-93)

**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 LACUC or to the Institutional Official. In all instances these allegations shall be immediately forwarded to the LACUC 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 LACUC 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.

LACUC PROCEDURES FOR THE INVESTIGATION OF A COMPLAINT: The LACUC 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 LACUC Chair will acknowledge receipt of the allegation to the complainant in writing. The LACUC Chair will present all allegations either to a convened subcommittee or to the LACUC during its next meeting. The LACUC 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 LACUC may, with the concurrence of the Institutional Official, suspend an activity pending the outcome of a full investigation.** The LACUC 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 results of the investigation will be presented during a formal meeting of the LACUC and all committee members will be given the opportunity to present minority views. The LACUC 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 LACUC 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 LACUC and reviewing the results of the LACUC 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. LACUC is empowered by USDA Regulation and PHS policy to suspend a previously approved project pending review by the Institutional Official. In this case, and whenever LACUC suspends an activity involving animals (for example when activities are suspended pending the outcome of an investigation), the Institutional Official must report the action with a full explanation to APHIS and any Federal funding agency including OLAW.

(Approved 07-27-93)

TIME LIMITATIONS FOR VARIOUS LACUC RESPONSE REQUESTS

Continuing review questionnaires and requests for protocol renewal (i.e., three year *de novo* review) will be mailed to investigators at least two (2) months prior to the continuing review or the renewal due date.

The Committee recommends allowing at least one (1) month for investigators to respond to:

1. Return of continuing review questionnaires or submission of responses to continuing review concerns
2. Requests for renewal petitions
3. Responses to restrictions placed on protocol actions by the LACUC.

After this time, closure or withdrawal action may be initiated and investigators will be promptly notified in writing.

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 (LACUC). 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 LACUC.
- B) Transfer of all animals between active animal use protocols will be done by the LAR and LACUC as described in the LACUC "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 LACUC.

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

Animal models Requiring LACUC 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, an approved protocol is still required.

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

(03-94)

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

It is the goal of the Laboratory Animal Care and Use Committee (LACUC) to ensure the proper and humane care and use of laboratory animals at Wright State University while not unnecessarily burdening Wright State University investigators. The following form is to aid investigators in determining if a protocol is appropriate for an activity involving laboratory **animals and/or tissues**. The LACUC will review the completed form and advise you in writing whether an animal use protocol is necessary. If it is, a protocol form will be forwarded to you. If a protocol is not required, no further action is required regarding this 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 killed 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.

In general, an approved protocol is not required when a “stock” animal product is purchased from a supplier. An example might include purchase of a stocked antibody from a biomedical company. However, if a product is made or an animal is used expressly for a specific purpose, that purpose must be covered by an animal use protocol. Examples of this situation might include purchase of custom antibodies or purchase of animal-utilizing test services.

Wright State University
Proposed Activities Involving the Use of Laboratory Animals and/or Tissues

Please Type. Submit the signed original and 2 copies of this form and any attached narrative(s) to Research and Sponsored Programs, Room 201J, University Hall. The LACUC secretary may be contacted by phone (937-775-3332), by FAX (937-775-3781), or through e-mail (christine.piekkola@wright.edu).

1. Name _____ Dept.: _____

2. Title of Project/Course: _____

3. Provide a concise description of what biological material(s) will be used, as well as how and where this material will be acquired.

4. Provide a concise description of your proposed activities.

Signature of Principal Investigator

Date

-
LACUC Recommendation:

Exempt

Requires a Protocol

Further Information Required

LACUC Chair Signature

Date

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) Individuals adopting animals should:
 - 1) agree not to sell or give away the animal.
 - 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.
- C) Dogs and cats over five (5) weeks of age shall be neutered prior to release.
- D) Though a nominal charge may be assessed for neutering a prospective pet, there will be no fee charged for adoption.

A recognized humane organization can adopt multiple animals through a cooperative arrangement

Animal Adoption Record

Animal Adoption Record
Laboratory Animal Resources, Wright State University

1. I accept the adoption of the animal described below 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 below 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 below 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 below 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 below.
5. I have read and understand the foregoing and voluntarily sign this Animal Adoption Record with full knowledge of its significance.

Species _____ Breed or Type _____

Identifying Marks/ Tattoo number/ Color _____

Sex _____ Age _____ Weight _____

Vaccination History of Animal

Medical/Behavioral Information

Name (Print) _____

Address _____

Telephone _____

Signature _____ Date _____

Signature of LAR Representative _____

ANNUAL REVIEW OF PROTOCOLS BY FULL LACUC

The Committee established that protocols involving the following procedures should automatically be reviewed annually by the full Committee in lieu of review by the administrative (Designated Reviewer) review method:

1. those involving Pain Category "D"
2. those using neuromuscular blocking agents
3. those involving multi-survival surgeries
4. those involving primates

This form of annual review is designed to provide greater oversight, it is not intended to be a complete rewrite.

All other protocols shall be reviewed annually by the administrative (Designated Reviewer) review method. This administrative review may result in:

1. review by the full Committee
2. requests for additional clarifications/additional information from the investigator before a final recommendation can be given.

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

This policy applies to recent funding applications which contain animal use activities and where the sponsor allows submission of institutional approval of such activities under the “Just-in-Time” or similar concept (e.g., a Public Health Service agency such as NIH or CDC or the American Heart Association).

It is the university’s responsibility to assure that all animal use activities described in these proposals have been approved by the LACUC. As part of this process and to facilitate timely submission of “Just-in-Time” documentation when requested by the sponsor, the following procedure is to be followed:

1. RSP will notify investigators of the need to submit “Just-in-Time” information.
2. The PI must review the activities proposed in the funding application to ensure that the activities have been approved by the LACUC or, alternatively, prepare and submit an Animal Use Protocol for LACUC review incorporating the proposed animal activities. Once all of the animal activities have been approved, the investigator must provide RSP with the following information:
 - a. Identify the animal use protocol(s) [i.e., the AUP Number(s)] under which the proposed animal studies are approved.
 - b. Submit for the LACUC the appropriately highlighted sections in the grant proposal that concern animal studies AND a highlighted copy of the relevant AUP(s) section(s).

Once this information has been received by RSP, it will be administratively reviewed and investigator’s will be notified of the outcome of this review.

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. This policy is implemented by the Laboratory Animals Care and Use Committee (LACUC).

1. Animals which do not require euthanasia and are considered safe to be handled may be transferred to another approved project at the university, transferred for approved activities to other appropriate federally licensed facilities, or adopted as a companion pet in accordance with LACUC policy for Adoption of a Companion Pet. 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. Any institution asking for the transfer of live animals must submit a written request for approval by the full LACUC.
2. Requests for the transfer or disposition of animals other than as indicated in Item 1 above will be considered by LACUC 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 LACUC on a case-by-case basis.
5. All other remains will be disposed of in accordance with all State and Federal Regulations.

(Approved 09-07-95)

**DISPOSITION OF EXCESS LIVE ANIMALS AND LIVE ANIMALS RETURNED TO
THE WRIGHT STATE UNIVERSITY LABORATORY ANIMAL RESOURCES**

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:

- 1) Animals will be transferred to active animal use protocols which contain requirements for the species in question.
- 2) If animals cannot be used as described in (1) and they are in appropriate health, they may be adopted in accordance with Wright State University's "Policy for Adoption of a Companion Pet".
- 3) If animals cannot be utilized as described in (1) or (2) they will be euthanized as described in Laboratory Animal Resources Standard Operating Procedures.

EFFECTIVE START DATE FOR PROTOCOLS/AMENDMENTS

The Committee determined that the effective start date and subsequent latest approval (i.e. annual updates) for protocols and the effective dates of amendments will be the date of signature on the action forms by the Institutional Official.

EUTHANASIA CERTIFICATION PROCEDURES

Investigators or their designate must be certified in the euthanasia method approved in the protocol. Investigators or designates of active protocols are considered to be certified. Those submitting new protocols require observation by the Veterinarian to become certified (previous experience is not grounds for an exemption). Investigators are responsible for assuring that all their personnel carrying out euthanasia are properly trained in the method approved in the protocol.

MONITORING OF WSU'S ANIMAL CARE PROGRAM BY THE LACUC

LACUC has approved the following mechanisms to provide periodic monitoring for compliance with LACUC policy and Program of Animal Care:

1. 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.
2. Instruction of researchers and staff in "whistle blower" mechanisms and responsibilities.
3. Training certification through LAR with education of all those who handle or use animals.
4. LACUC may request investigators to meet with the committee to discuss the review of their protocols.
5. Periodic reminders of policy and updates in requirements.
6. Development of SOPs for animal handling and use.

(6/2/93)

NATIONAL SCIENCE FAIR PROJECTS

The LACUC recognizes the validity of responsible animal use in the educational process. To support educational efforts at local schools, the LACUC 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 LACUC 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 LACUC 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 LACUC 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 LACUC 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 by the full LACUC of an amendment to the protocol.

(9/2/93)

PERSONNEL CHANGES TO APPROVED PROTOCOLS

It is the investigators' responsibility to request formal training from LAR for all personnel who handle animals in any way. This includes students in short term projects and other temporary help. These individuals must be registered with LAR, with the list available for LACUC inspection. If the change in personnel involves continuing employees or key personnel, this information must be submitted to LACUC as a protocol amendment.

(For details regarding formal training, see the Policy entitled Training Program for Animal Use/Handling.)

ASSIGNMENT OF PRIMARY REVIEWERS

A primary reviewer will be assigned by the Chair to each protocol to be considered for approval by full LACUC Committee review. It is the responsibility of the primary reviewer to thoroughly review the petition and may contact the investigator prior to committee review with any questions, concerns, or needed clarifications. The primary reviewer will present a brief synopsis of the protocol to the LACUC prior to its full discussion and review.

PROPOSALS CONTAINING PROPRIETARY DRUGS

LACUC will review the use of non-specified drugs or other such agents provided the investigator documents that these agents are proprietary 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) is generally preferable for reliable research results. In specific cases the use of non-purpose-bred animals may be necessary due to behavioral or other reasons. When justified by experimental design, conditioned random-source dogs and cats may be purchased from suppliers that are either a) Fully Accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care, Int. (AAALAC), or b) biannually 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.

SUPPORTED USE OF ANIMALS AT OTHER INSTITUTIONS BY WRIGHT STATE UNIVERSITY

From time to time employees of Wright State University support use of animals at other institutions by expending funds for animal use at these institutions, and/or by spending time working on projects involving animal use while at these institutions. Examples of this type of situation include: production of a custom antibody by a vendor, compound testing involving animals at another site, faculty use of animals at another institution, animal - utilizing collaborations with an investigator at another institution, or use of animals while on a sabbatical. It is the responsibility of Wright State University's Laboratory Animal Care and Use Committee (LACUC) to monitor these activities. The degree of monitoring required depends on three factors: 1) the investigator's appointment, 2) the source of funds used in the project, and 3) USDA and Public Health Service status of the other institution.

Depending on the three monitoring factors just mentioned, the Wright State investigator (PI) has varying obligations, as indicated in the attached Table 1. It is their responsibility to provide the appropriate information (mentioned in Table 1) to the LACUC. Similarly, it is the responsibility of the PI to inform the LACUC of any significant impending change(s) in these monitoring factors. This notification must be made at a time so that review responsibilities of the LACUC can be completed, using normal LACUC procedures, prior to implementing the change

If protocol review by the LACUC is indicated from Table 1, a protocol should be submitted to the Research and Sponsored Programs office using their regular animal use protocol form following their current procedures. The LACUC will then review the protocol by whichever standard mechanism is appropriate.

If Table 1 calls for 1) proof of PHS Assurance and/or USDA License as well as proof of protocol approval by the other institution, 2) a brief description of the requested animal use, and 3) assurance that the animal use is not duplicative, the appropriate information may be transmitted by letter to the Research and Sponsored Programs office. Database(s) searched to verify that the animal use is not duplicative should be cited. The Chairperson of the LACUC and the WSU Veterinarian will review the information and may: 1) approve the activity on behalf of the LACUC, if both agree, 2) request further information, or 3) forward the information to the LACUC for full consideration.

Prior to undertaking any Wright State - supported use of animals at another institution, the LACUC (or its representatives) must review the appropriate information and approve the activity.

Collaborative arrangements involving institutions outside the United States are not explicitly considered here and will be determined on a case by case basis.

This policy statement shall be distributed to all Wright State University PI's who participate in Wright State supported use of animals at other institutions.

TABLE 1

Source of Funds Used for the research --	WSU Funds requiring Assurance. (This includes NIH, NSF, DoD and most other federal funds)			Other WSU Funds. (This includes internal or external funds which do not require an Assurance.)			No WSU funds are expended for the animal use.		
Research Site Status --	Institution has a PHS Assurance ³	Institution has a USDA License.	Institution has no Assurance or License.	Institution has a PHS Assurance	Institution has a USDA License	Institution has no Assurance or License.	Institution has a PHS Assurance	Institution has a USDA License.	Institution has no Assurance or License.
<p>A. Investigator not directly using animals. WSU administered funds expended for animal use.</p>	<p>The PI supplies the LACUC with: 1) proof of other institution's PHS Assurance and other institution's protocol approval, 2) brief animal use description, 3) assurance that animal use is not duplicative.</p>	<p>Not normally allowed. Must be authorized by the WSU Institutional Official. (If authorized, would require LACUC protocol review and semi annual inspection of the animal use site by the LACUC.)</p>	<p>The PI supplies the LACUC with: 1) proof of other institution's PHS Assurance and other institution's protocol approval, 2) brief animal use description, 3) assurance that animal use is not duplicative.</p>	<p>The PI supplies the LACUC with proof of other institution's USDA License and protocol approval. Further, the LACUC must review and approve the protocol.</p>	<p>Not normally allowed. Must be authorized by the WSU Institutional Official. (If authorized, would require LACUC protocol review and semi annual inspection of the animal use site by the LACUC.)</p>	<p>The LACUC need not be notified.</p>			
<p>B. Investigator directly involved in animal use when Investigator's WSU Appointment is -</p>									

1. Fully Affiliated ¹	As above	As above	As above	As above	As above	As above	The PI supplies the LACUC with: 1) proof of the other institution's PHS Assurance or USDA License and other institution's protocol approval, 2) brief animal use description , 3) assurance that animal use is not duplicative .	Not normally allowed. Must be authorized by the WSU Institutional Official. If authorized, would require LACUC protocol review and semi annual inspection of the animal use site by the LACUC.)
2. Partially Affiliated ²							The LACUC need not be notified.	

Footnote:

- 1 All WSU employees and SoM Institutional Appointments
- 2 Adjunct and voluntary appointments
- 3 Federal institutions such as the Air Force will be treated as Assured institutions.

**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 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 LACUC 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 C under LACUC Appendix 1, 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 period or one (1) year following its most recent Continuing Review, whichever is earlier, 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

The training program is divided into three (3) components as outlined below:

1. The introductory component 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.
2. 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).
3. The final component will utilize interactive demonstrations performed by researchers to assure LAR staff that these researchers are prepared to conduct unsupervised animal-use activities. This assurance must be met by all appropriate investigators and technicians for each technique that will be performed and for each species that will be involved.

All investigators new to the university will be required to attend the mandatory sessions before being permitted to carry out any type of research. An interim certification, to be granted based on previous experience and LAR supervised observation of techniques, may be issued in order to allow an incoming, experienced investigator to continue research while awaiting their specific training session(s) to be scheduled. This interim certification must be requested in writing to the LACUC with evidence of previous experience included.

The committee recognizes that there may be a situation in which it may not be possible for a new investigator or technician to expeditiously attend a WSU-sponsored training session or to qualify for an interim certification. For this reason, the LACUC has authorized completion of the Veteran's Administration web-based tutorial entitled "Working with the IACUC (non-VA version)" and successful completion of the on-line examination as meeting the training requirements subject to the following:

- A. Satisfactory completion of the on-line examination and recording of the score under the Wright State University institutional affiliation.
- B. Approval is valid for no more that six (6) months during which time the WSU-sponsored training session must be completed

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