

LACUC POLICIES AND PROCEDURES

AT

WRIGHT STATE UNIVERSITY

[Revised and Approved March 2010]

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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.

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

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.

(Approved 5/7/09)

COMMITTEE STRUCTURE

GENERAL COMMITTEE STRUCTURE

(5/7/2009)

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.

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 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. Attend the introductory training for LACUC 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 LACUC 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. 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 voting LACUC 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 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.

(Approved 5/7/09)

PROCEDURES

GENERAL LACUC REVIEW/APPROVAL PROCEDURES

1. Electronic Submissions and Notifications

- a. To the extent possible, certain types of Committee business will be conducted electronically through the LACUC “Laboratory Animal Care and Use Committee, Protocol Management System” at <<http://lacuc.wright.edu/>>.
- 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 the proposed action (e.g., “Forms” to submit an amendment or submit a 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. Amendments and annual continuing reviews will generally use the “Designated Review” process unless full committee review is required by federal regulations or these policies and procedures. Any amendment to a protocol or continuing review which is considered confidential will automatically be sent for full committee review, unless the amendment only involves a minor personnel change. Any protocol that seeks to change its pain category through amendment will automatically be sent for full committee review.
- b. Designated Review involves protocol review by a subcommittee of at least two LACUC members appointed by the Chair (may include the chair as one of the appointed reviewers), 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). In the case of continuing reviews, the Designated Review subcommittee will usually consist of the Chair and the Veterinarian unless either is on the protocol.
- c. In review of amendments or continuing reviews all members have access to the documents. 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 recommend approval of the protocol, require modifications to secure a recommendation of approval of the protocol, or refer the protocol to the full LACUC for review. A recommendation for Approval by a subcommittee MUST be by consensus.

- d. Such Designated Review shall be followed by notification of the outcome to the full Committee at the next LACUC meeting.
3. New protocol applications are reviewed by Full Committee Review.
 4. 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 LACUC member (usually the Veterinarian) with notification of the LACUC. All LACUC 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. Approval of these revised protocols will be given by the IACUC, then forwarded to both the IACUC Chair and the Institutional Official for signatures indicating official approval.

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. Closures of protocols are carried out by Research and Sponsored Programs (RSP) with notification to LACUC, the Principal Investigator and Laboratory Animal Resources.
6. The transfer of animals from one approved protocol to another approved protocol must be approved by the LACUC as part of the approved protocol (i.e., either at original review or by amendment).

(Revision Approved 3/4/10)

PROCESSING NEW ANIMAL USE PROTOCOLS

I. Veterinarian Review and Consultation:

Prior to submission to Research and Sponsored Programs (RSP), protocols must be reviewed by the LAR Director/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 end-point 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 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 makes recommendations for changes to be made to the protocol. The investigator should consider carefully the recommendations of the Veterinarian, and modify the protocol as appropriate. The Veterinarian then endorses 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, endorsement may be withheld. The PI may still submit this protocol to RSP for review.

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 may be forwarded to RSP (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 and alternate 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 presents a short synopsis of the protocol followed by a discussion of the protocol.

- D) The committee will vote to recommend: approval, approval 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 recommended if the committee considers the clarification is sufficiently minor or straightforward so that the Chair and Veterinarian can indicate the modifications/clarifications are adequate and recommend approval to the Institutional Official.

IV. Outcomes of LACUC Actions:

- A) If the protocol is recommended for approval:
- 1) The LACUC chair will sign a notice of approval and forward it to the Institutional Official for signature and full approval. (Note: Approval requires the signature of the Institutional Official).
 - 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 may begin.
- 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. The LACUC will consider a protocol 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 or alternate Veterinarian) will review the response and either indicate that it is adequate and proceed as in Section IV.A. or request that the response be sent 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 within 90 days. The LACUC will consider a protocol withdrawn if a timely response is not received.
 - 2) Upon receipt of the PI's response to RSP, the revised protocol will be reviewed by full committee at the next meeting.
- 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., 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. 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"

(Approved 6/4/09)

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.

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 LACUC review and approval of the same protocol must submit the DoD-prescribed form to the LACUC in lieu of the WSU petition form.

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/>) under the "animals" link for:

1. Research activities
2. Teaching activities
3. Amendments
4. Continuing Review
5. Exempt Activities

In addition, the petition for amending a protocol or an annual continuing review petition is currently available through the LACUC Protocol Management System at <http://lacuc.wright.edu/>.

NOTIFICATIONS

The PI will be notified by RSP that a continuing review or a renewal of a protocol is due at least two (2) months prior to either its date for annual review or its expiration date, respectively. The PI will be asked for a response before the deadline. If a response is not obtained, the protocol will be inactivated.

(Approved 5/7/2009)

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.
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 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 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 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 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 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."

(Approved - 5/7/2009)

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 result(s) of the investigation will be presented in executive session 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. The LACUC, 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 LACUC to the Institutional Official.

(Approved 5/7/2009)

WSU IACUC and WPAFB IACUC Parallel Review Process

Guidelines for Submission and Review of Animal Protocols

1. Protocol format and synchronizing the parallel review process

- 1.1 AUP format. The DoD Format (currently in use at WPAFB) will be adopted with the following modifications:
- a) The cover page will contain two AUP numbers for identification at both institutions
 - b) Signature pages from both WSU and WPAFB with assurance numbers for both institutions will be appended to all forms, including the AUP, amendments and continuing reviews.
 - c) Both the WPAFB and the WSU IACUCs will maintain copies of all documents
- 1.2 Approval Date. The approval date for a protocol is the date at which all signatures are obtained, with the last signature being the Institutional Official at Wright State University.
- 1.3 Protocol Submission. The investigator will submit all documents and the appropriate number of copies to the WPAFB IACUC. The WPAFB IACUC office will then forward the necessary copies to the WSU IACUC. The deadline for submission of new protocols is the 1st of each month.

2. Review of Animal Use Protocols

2.1 Procedural Outline

- a) New AUPs will be distributed to all committee members of the WSU and WPAFB IACUC by the respective administrative offices.
- b) Either of two possible WSU review processes may occur:
 - (1) Designated Reviewer Process: Generally, this will be conducted at the WPAFB IACUC meeting on the 3rd Wednesday of the same month. Alternatively....
 - (2) Full-Committee Review Process. Generally, this will be conducted at the WSU IACUC meeting on the 1st Thursday of the following month.
- c) The earliest possible committee review is via the designated reviewer process on the 3rd Wednesday of the current month (at WPAFB)
- d) The WSU IACUC Chair will designate at least one (1) member as university representative(s) to review AUPs submitted for IACUC approval – *the designated reviewer(s)*.
- e) The WSU IACUC members will be advised about whom to contact with any questions/concerns about the AUP prior to WPAFB committee review. This contact will usually be the designated reviewer or one of the designated reviewers.
- f) Any IACUC member (WSU or WPAFB) may request a Full-Committee review. This request must be submitted to either the WSU IACUC Chair or the WPAFB Chair before the WPAFB IACUC meeting on the 3rd Wednesday of the month

- g) If there is no request for a Full Committee review, then the *Designated Reviewer Process* will be used by WSU at the WPAFB IACUC meeting.

2.2 Designated Reviewer Process

- a) Generally, the review will be conducted at the WPAFB IACUC meeting on the 3rd Wednesday of the month.
- b) The WSU IACUC will delegate at least one (1) member as a university representative(s) – the designated reviewer(s).
- c) The *designated reviewer(s)* will attend the WPAFB IACUC meeting and participate in the discussion of the AUP. The policy and guidelines of the WPAFB IACUC will prevail. The WSU *designated reviewer(s)* may exercise any of the following actions:
 - (1) Recommend Approval
 - (2) Recommend Conditional Approval. Specify restrictions or clarification that require a response from the PI (i.e., revisions to the AUP)
 - (3) Defer the AUP for Full-Committee review at the next WSU IACUC meeting.
- d) If the AUP is given Conditional Approval (pending response to restrictions), then the designated reviewer(s) have the right to review and approve the IACUC letter outlining the restrictions, prior to its distribution to the PI (See Section 2.4 of this procedure)
- e) A brief written account of the IACUC review of the AUP and outcome of the review vote will appear in the WSU IACUC minutes.

2.3 Full Committee Review Process

- a) Generally, this review will be conducted at the WSU IACUC meeting on the 1st Thursday of the following month.
- b) WPAFB IACUC members will attend the WSU meeting. The number of WPAFB IACUC members is left to the discretion of that committee, but at least one designated reviewer representing WPAFB IACUC is required.
- c) Business will be conducted in accordance with standard WSU IACUC procedures with members from both IACUCs providing discussion of the protocol and voting. The results of the vote will be reported independently in each committee's minutes. The possible outcomes of a Full-Committee Review include:
 - (1) Recommend Approval
 - (2) Recommend Conditional Approval. Specify restrictions or clarifications that require a response from the PI (i.e., revisions to the AUP) and can be reviewed and approved by the Designated Reviewer Process upon receipt from the PI. (See section 2.4.a of this procedure)
 - (3) Deferral. Specify restrictions or clarifications that require a response from the PI (i.e., revisions to the AUP) but must be reviewed by the Full Committee Review Process upon receipt. (See section 2.4.a of this procedure)

- (4) Withhold Approval. Express the Committee's decision and reasons for stating that the protocol is not acceptable. The principal investigator shall be given the opportunity to respond to the Committee's decision in person or in writing. The IACUC may consider a decision to withhold approval, with appropriate documentation in the Committee's minutes, upon the receipt of additional information.

2.4 Response to Restrictions/Protocol Revisions

- a) For AUPs that were 'Approved' but with restrictions, the Designated Reviewer Process will be used. The response received from the PI regarding review of the AUP will be distributed to both IACUCs and evaluated by the subcommittee (WPAFB) and designated reviewer(s) (WSU). If more than one designated reviewer from WSU was appointed, the evaluation and approval of the Response to Restrictions must be a unanimous decision by all appointed designated reviewers.
- b) For AUPs that were 'Deferred or Tabled', the Full-Committee Process will be used. The responses received from the PI regarding review of the AUP will be distributed to both IACUCs and evaluated by both committees at the next regularly scheduled meeting of the WSU committee (generally the 1st Thursday of the month), as outlined above in Section 2.3 of this procedure.

3. Amendments

- 3.1 All amendments to AUPs will require the written approval of both the WSU IACUC and the WPAFB IACUC
- 3.2 The PI will submit AUP amendments to the WPAFB IACUC office, and a copy will be forwarded to the WSU IACUC office.
- 3.3 The amendment will be distributed to the chairs of the WSU IACUC and the WPAFB IACUC. The amendment will be evaluated using the standard procedures of each IACUC.
- 3.4 The Amendment will be distributed to all members of the WSU IACUC.
- 3.5 Members will be advised about whom to contact with questions/concerns about the Amendment.
- 3.6 Any member can request that the Amendment be discussed at a Full-Committee session (as described in Section 2.3 of this procedure)
- 3.7 If there is no request for a Full-Committee process, then the Designated Reviewer Process will be used by WSU to act on the Amendment (as described in Section 2.3 of this procedure)

4. Continuing Review Process

- 4.1 The standard WPAFB IACUC Continuing (Annual) Review Form will be used.
- 4.2 Continuing Review Forms will be distributed to investigators with active Animal Use Protocols by the WPAFB IACUC office.
- 4.3 Completed Continuing Review Forms will be returned to the WPAFB IACUC office by the investigator
- 4.4 The WPAFB IACUC office will forward the appropriate number of copies of the completed Continuing Review Form to the WSU IACUC office.

- 4.5 Completed Continuing Review Forms will be distributed to the chairs and/or designated reviewers by the appropriate administrative office.
- 4.6 AUPs will be subject to the same criteria currently in place for automatic full committee review: e.g. multiple survival surgery, nonhuman primate research, use of paralytics, pain category D.
- 4.7 Any member can request that the completed Continuing Review be discussed at a Full-Committee session.
- 4.8 If there is no request for a Full-Committee process, then the *Designated Reviewer Process* will be used by WSU to act on the completed Continuing Review.

[APPROVED 7/2/09]

TIME LIMITATIONS FOR VARIOUS LACUC RESPONSE REQUESTS

Notification of due dates for continuing reviews or 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 two (2) months for investigators to respond to:

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

After the two month time period, closure or withdrawal action may be initiated: investigators will be promptly notified in writing before this final action is initiated.

(Approved 5/7/2009)

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 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 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 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 LACUC.

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 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. 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. The following form should be filled out to determine if an activity is exempt or requires an animal use protocol.

The production of animals at a non-WSU facility must be done under an approved protocol at that facility before those animals can be purchased by a WSU investigator.

(Approved 6/4/09)

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.

(Approved 5/7/2009)

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 5/7/2009)

ANNUAL CONTINUING REVIEW OF PROTOCOLS BY FULL LACUC

The Committee established that confidential protocols should automatically be reviewed annually by the full Committee in lieu of review by the Designated Review method.

The annual review form is designed to provide greater oversight. It is not intended to be a complete rewrite of the protocol.

All other continuing review requests shall be reviewed annually by the Designated Review method. This 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.
3. closure of a protocol at the Principal Investigator's request.

(REVISION APPROVED 3/4/10)

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 LACUC with the information submitted to the sponsoring agency or agencies in the relevant grant application. If the LACUC 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 LACUC approval.

(APPROVED 6/4/09)

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 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 6/4/09)

DISPOSITION OF EXCESS LIVE ANIMALS

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.

(Approved 6/4/09)

EFFECTIVE START DATE FOR PROTOCOLS/AMENDMENTS

The effective start date for new protocols and amendments will be the date of signature on the approval form by the Institutional Official. The effective start date for new protocols will determine the month and day of the anniversary date for the continuing review deadline; however, if a continuing review is not approved on or before the anniversary date, the Principal Investigator will be notified immediately that the protocol has expired and all animal activities under that protocol are suspended pending submission and approval of a new protocol.

(Approved 6/4/09)

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. Investigators are responsible for assuring that all their personnel carrying out euthanasia are properly trained in the method approved in the protocol.

(Approved 6/4/09)

MONITORING OF WSU'S ANIMAL CARE PROGRAM BY THE LACUC

LACUC has approved the following mechanisms to provide periodic monitoring for compliance with LACUC 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" (see <http://www.wright.edu/rsp/Animals/Assurance.doc>).
2. 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.
3. Instruction of researchers and staff in "whistle blower" mechanisms and responsibilities.
4. Training certification through LAR with education of all those who handle or use animals.
5. LACUC may request investigators to meet with the committee to discuss the review of their protocols.
6. Periodic reminders of policy and updates in requirements.
7. Development of SOPs for animal handling and use.
8. Monthly inspection of non-LAR housing facilities by the veterinary staff.

(Approved 6/4/09)

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.

(Approved 6/4/09)

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.

(Approved 6/4/09)

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.

(Approved 6/4/09)

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.

(Approved 6/4/09)

PERSONNEL CHANGES TO APPROVED PROTOCOLS

It is the investigators' responsibility to request all training (as stipulated in Training Program for Animal Use/Handling) from LAR for all personnel on a Animal Use Protocol. 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.)

(Approved 6/4/09)

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.

(Approved 6/4/09)

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/confidential information and the company does not allow their identification.

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

(Approved 6/4/09)

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.

(Approved 6/4/09)

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 LACUC 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 LACUC 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 LACUC 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 LACUC must prospectively review and approve the proposed research. The LACUC 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 LACUC 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 will 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 LACUC 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.

(Approved 6/4/09)

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 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.

(Approved 6/4/09)

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 or its latest annual Continuing Review expiration date, 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.

(Approved 6/4/09)

TRAINING PROGRAM FOR ANIMAL USE/HANDLING

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

1. The introductory component (Introductory Course in Laboratory 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. All individuals will also be required to complete the online Occupational Health and Safety program.
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). 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.
3. The qualifications of personnel conducting specific procedures in animals will be ensured through LACUC 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 LACUC prior to unsupervised animal-use activities.

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.

(Approved 7/2/09)