

**WRIGHT STATE UNIVERSITY**  
**Assurance No. 3632-01**  
**Animal Welfare Assurance**  
**In Accordance With The PHS Policy for**  
**Humane Care and Use of Laboratory Animals**

I, Robert E.W. Fyffe, Ph.D., Vice President for Research and Graduate Studies, as named Institutional Official for animal care and use at Wright State University, hereinafter referred to as "Institution," hereby gives assurance that it will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

I. Applicability of Assurance

This assurance is applicable to all educational, research, research training, experimentation, biological testing, and related activities, hereinafter referred to as activities, involving live, vertebrate animals, supported by the Public Health Service (PHS) and conducted at this Institution, or at another Institution as a consequence of the subgranting or subcontracting of any PHS activity conducted or supported by this Institution.

- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:

*[List every branch and major component covered by this Assurance.]:*

Biological Sciences and Health Sciences Facility	12,617 nasf
Fawcett Hall Facility	355 nasf
Receiving/Conditioning Area	1,545 nasf inside and 20,000 nasf fenced lots
Cox Research Institute Facility	3,877 nasf

The "nasf" equals the total "net assignable square feet" in each facility.

II. Institutional Commitment

- A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."
- C. The Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, as well as all other applicable laws and regulations pertaining to animal care and use.

- D. This Institution has established and will maintain a program for activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals, 2011 and future additions (Guide).
- E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

### III. Institutional Program for Animal Care and Use

- A. The lines of authority and responsibility for administering the program and ensuring compliance with this Policy are described below and outlined in a chart included as Attachment #1

The Laboratory Animal Resources (LAR) Program is administratively and budgetarily a component of the School of Medicine. All Institutional activities utilizing live, vertebrate animals are the responsibility of the Program. The Director and Associate Director are board certified veterinarians holding 100% FTE appointments. The remaining staff is composed of:

Operations Coordinator –Licensed Veterinary Technician, AALAS Certified Laboratory Animal Technologist, Certified Manager of Laboratory Animal Resources. 27 years experience in laboratory animal care and use and administration, 9 years with LAR Program.

Laboratory Animal Technologist - AALAS Certified Laboratory Animal Technologist  
25 years experience in laboratory animal medicine

Laboratory Animal Technologist - AALAS Certified Laboratory Animal Technologist  
31 years experience in laboratory animal medicine

(3) Assistant Laboratory Animal Technician  
1-3 years experience in laboratory animal medicine

The LAR Program was established by and as a component of the School of Medicine in 1975. The requirements were to develop, implement, establish and maintain a total program of animal care and use, with University-wide responsibility, in compliance with the Guide, Federal and State statutes and regulations, and University policies and values. The animal care and use program has been AAALAC accredited since 1995 with Full Accreditation last awarded March 10, 2010. The Institution, especially the School of Medicine, recognizes its role and responsibilities and is fully supportive.

- B. The qualifications, authority and responsibility of the veterinarians who will participate in the program include:

Gregory P. Boivin, D.V.M., ACLAM Diplomate  
Director, Laboratory Animal Resources Program  
Attending Veterinarian  
Professor, Pathology and Orthopaedic Surgery  
22 years experience in laboratory animal medicine

#### 100% FTE Appointment

The Attending Veterinarian has full responsibility and authority for development, implementation, establishment and maintenance of the total program involving the utilization of laboratory animals. The program must be in compliance with the Guide, all Federal and State regulations and all University policies and rules. He is responsible for the administration (including budgeting), daily management, clinical requirements, and operations with policy making authority relative thereto. He reports to the Associate Dean for Research Affairs, Boonshoft School of Medicine, Wright State University. He has the responsibility and authority, through appropriate channels, to ensure that the Program and its utilizers meet or exceed the established standards/policies of NIH, USDA, and other concerned agencies. Dr Boivin has full access to all animals in the animal care and use program.

Emily S. Dudley, D.V.M.

Clinical Veterinarian, Laboratory Animal Resources Program

14 years experience as a clinical veterinarian, including 4 years exclusively in laboratory animal medicine

100% FTE Appointment

Wright State University is fortunate to have two veterinarians, serving as backup veterinarians for the University during the absence of Dr. Boivin, LAR Director, or Dr. Dudley, LAR Clinical Veterinarian, are

Karyn Armstrong DVM, ACLAM Diplomate

Army Comparative Medicine, Air Force Research Laboratory

Wright Patterson Air Force Base, Dayton, OH

Kevin Corcoran, D.V.M., ACLAM Diplomate

Laboratory Animal Veterinarian

Xenia, OH

Dr. Corcoran provides emergency backup veterinary care in the absence of the previously mentioned three veterinarians. He became an ACLAM Diplomate in 1990.

Emergency contact numbers (home, work, and cell) for all veterinarians, as well as other emergency contact personnel, are conspicuously posted in all animal facilities. The University's Public Safety Office and Police Dispatch Office also maintain a list of emergency contact personnel which includes the list of all available veterinarians.

- B. The Institution has established a Laboratory Animal Care and Use Committee (LACUC), which is qualified through the experience and expertise of its members to oversee the Institution's animal program, facilities, and procedures. The LACUC consists of thirteen (13) members (plus twelve [12] alternates and one [1] non-voting member). Its membership meets the compositional requirements set forth in the PHS Policy at IV.A.3.b. Attached to these assurances (Attachment 2) is a list of the names, degrees, position titles, specialties and Institutional affiliations of the current LACUC Chairman and members.

D. The LACUC will:

1. Review at least once every six months (semi-annually) the Institution's program for humane care and use of animals, using the Guide as a basis for evaluation. All LACUC members are invited to participate in the semi-annual review. The LACUC procedures for conducting semiannual program evaluations are:
  - a. The semiannual program review is conducted at a convened meeting (regular or special).
  - b. Each member receives or has received a copy of the Guide, the previous semiannual program and facilities inspection report, LAR's program of laboratory animal care and use (containing their operational policies), LACUC's policies and procedures manual (containing their charges and responsibilities), and WSU's Institutional Animal Care and Use Program Evaluation checklist (modeled after that suggested by the Office of Laboratory Animal Welfare [OLAW]) which reviews all aspects of the animal use program including administration (see 2b below for specifics).
  - c. In addition, agenda items for scheduled monthly LACUC meetings include program review, discussion, and/or recommended revisions to improve the level of care and to insure compliance.
  - d. As some members of the LACUC are active utilizers of laboratory animals, they are constantly reviewing the program relevant to their work.
2. Inspect at least once every six months (semi-annually) all of the Institution's animal facilities, including satellite facilities, laboratories using animals, and animal surgical sites, using the Guide as a basis for evaluation. The LACUC procedures for conducting semiannual facility inspections are:
  - a. At scheduled intervals, at least once every six months, each facility or area will be completely inspected by no less than two (2) LACUC voting members and the results discussed at a convened meeting (regular or special).
  - b. Included in the facilities inspections are inspections of animal care records, LACUC administrative records, LAR staff interviews, and random interviews with investigators holding active animal use protocols and other laboratory staff involved with animal care and utilization. The OLAW Semiannual Program and Facility Review Checklist will be used as the basis for the semiannual inspections.
  - c. Any item not in compliance with the Guide will be recorded and submitted to the Vice President for Research and Graduate Studies along with recommended corrective actions; items of non-compliance will also be reported to OLAW.
  - d. If significant deficiencies are found which threaten animal health, the Attending Veterinarian is to be notified immediately.
  - e. For PI controlled non-LAR animal housing sites, a copy of the approved protocol can be made available for the inspection team.

- f. At least one follow up inspection should be made of PI controlled non-LAR animal housing sites by at least two members of the immediate past inspection team. This inspection should occur between the regularly scheduled semi-annual inspections, at a time determined by the inspection team.
  - g. The date(s) of each inspection will be included with the annual Assurance Document update. WSU's semiannual facilities inspection is normally conducted in conjunction with their semiannual program evaluation.
  - h. All LACUC members are invited to participate in the semiannual program review and evaluation.
3. Prepare reports of the LACUC evaluations as set forth in the PHS Policy at IV.B.3. and submit the reports to the Institutional Official (Vice President for Research and Graduate Studies), Wright State University. The LACUC process for developing reports and submitting them to the Institutional Official are:
- a. The Chair prepares a draft report based, in part, upon the facilities inspection subcommittee reports and applicable program review results.
  - b. At a convened meeting, the draft report along with any additional facilities inspection or program review information, is discussed and compiled into a final report.
  - c. Deficiencies identified during the facilities and program reviews are detailed in the report with recommended corrective actions and deadlines for each correction. During a convened meeting, deficiencies are classified as either major, usually those directly affecting animal health, or minor in the semiannual report by the LACUC during the convened meeting.
  - d. Departures from the Guide are identified specifically and reasons for each departure are stated and reported to the IO in each semi-annual report in which the LACUC approved departure is in place.
  - e. This report, along with any minority opinions and/or recommendations, is endorsed by the Committee and forwarded to the Institutional Official.
4. Review concerns involving the care and use of animals at the Institution. The LACUC procedures for reviewing concerns are:
- a. Wright State has adopted a policy and has developed procedures for investigating concerns involving the care and use of animals at Wright State University. This information is specified in Procedures for Dealing with Allegations of Animal Mistreatment or Deficiencies in Their Care at Wright State University as contained within LACUC Policies and Procedures at Wright State University (Policies & Procedures). This is a publicly available document (distribution by Research and Sponsored Programs [RSP] and published on RSP's home page) that is available to all investigators.

- b. Mechanisms for reporting concerns are posted in the animal facilities and on the Wright State University RSP website with instructions on reporting animal welfare concerns and to whom those reports are to be sent.
  - c. Concern(s) involving the care and use of animals may be submitted to the LAR, SOM, LACUC, or the Vice President for Research and Graduate Studies (I.O.).
  - d. All such concerns will be presented to the LACUC for review, discussion, and suggested resolution, all of which will be recorded and kept on file. Every concern of which the LACUC is made aware will receive attention and responses will be documented.
  - e. All appropriate parties, including the Institutional Official and appropriate (e.g., Federal) oversight agencies, will be made aware, in writing, of the outcome(s).
  - f. Dependent upon the nature of the concern, the manner expressed and by whom, the LACUC, the LAR Director, or the Institutional Official, will respond to those initiating the concern(s).
  - g. Protection from reprisals for individuals reporting such concerns are assured through WSU's policy entitled Reporting the Mistreatment of Animals and Deficiencies in Their Care at Wright State University as contained within LACUC Policies and Procedures.
5. Make written recommendations to WSU's Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. Any such recommendations will be made in writing to the Institutional Official, the Vice President for Research and Graduate Studies, and records will be kept of all aspects thereof.
6. In accordance with PHS Policy IV.C.1-3, the LACUC shall review and approve, require modifications in (to secure approval), or withhold approval of those activities related to the care and use of animals as set forth in the PHS Policy at IV.C.1-3. All animal protocols must receive a full committee review. Amendments and continuing reviews of protocols are performed by designated review.

The LACUC procedures for full committee review are:

- a. After a preliminary review by the Veterinarian, completed requests for approval of animal utilization are submitted to the LACUC by the Principal Investigator (PI) for each project.
- b. Copies are provided to all LACUC members for discussion at the next scheduled monthly meeting, such discussion being led by a "primary reviewer." The primary reviewer is a LACUC member, assigned by the Chair, and not associated with the protocol. If any question arises prior to the LACUC meeting, additional details and/or a meeting with the PI may be requested by the primary reviewer.
- c. To hold a full committee review a convened meeting of a quorum of the LACUC must be held. Following PHS Policy Part IV.C.2 no member may participate in the LACUC review or approval of a research project in which the member has a conflicting interest (e.g. is personally involved in the project) except to provide information requested by the LACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.

Confirmation of a quorum is done by head count when a member is recused for a conflict of interest. A majority vote of the members constituting the quorum is required to approve a full committee review action. Minority opinions are allowed to accompany any action.

- d. There are 3 potential outcomes for full committee review. Outcomes of LACUC Actions are:
- 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 Laboratory Animal Resources.
    - 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 sent to designated review with modifications/clarifications required to secure approval:
    - 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 (within 90 days).
    - 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 A1-3 above, or request that the response be sent to the full committee. Please note all LACUC members have agreed **in advance in writing** that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. Any member of the LACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.
    - 3) The LACUC has approved this method of designated review during a convened meeting of the full LACUC.
    - 2) Upon receipt of the PI's response to RSP, the revised protocol will be reviewed by full committee at the next meeting.
  - C) 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. Designated Member Review of Continuing Reviews and Amendments
- A. Amendments and annual continuing reviews will generally use the "Designated Review" process unless full committee review is required by federal regulations. 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 personnel change not involving the Principal Investigator. 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). All members of the LACUC see the same document. 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.
- D. 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. When recommending approval all members of the designate member review must be in unanimous agreement of the decision. All DMR's review identical versions of the protocol. If modifications are requested in the DMR process, all reviewers will see the revised document for decision on approval.
- E. Such Designated Review shall be followed by notification of the outcome to the full Committee at the next LACUC meeting and to the Principal Investigator by letter. No activity can be initiated until full approval is received from the designated review team and signature of the IO and chairperson are received.

#### Designated Member Review of Protocols Requiring Modifications for Approval

- A. A subcommittee is assigned to review protocols requiring modifications to secure approval.
- B. Designated Member Review involves protocol review by at least two LACUC members appointed by the Chair (may include the chair as one of the appointed reviewers) All DMR members see the same document. The Designated Review subcommittee will usually consist of the Chair and the Veterinarian unless either is on the protocol.
- C. 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. When recommending approval all members of the designate member review must be in unanimous agreement of the decision. All DMR's review identical versions of the protocol. If modifications are requested in the DMR process, all reviewers will see the revised document for decision on approval.
- D. Such Designated Review shall be followed by notification of the outcome to the full Committee at the next LACUC meeting and to the Principal Investigator by letter. No activity can be initiated until full approval is received from the designated review team and signature of the IO and chairperson are received.



- E. Alternate members of the LACUC are appointed by the University President, receive training identical to full members, and are specifically designated to which member type they are an alternate. Alternate members may attend all meetings and replace (e.g., vote in place of) the member absent from a meeting for whom they are acting as an alternate. Alternates may also act as a member of the LACUC in authorizing clarifications of approved protocols, in authorizing amendments not requiring full committee action, and as members of Semiannual Program and Facility inspection teams. If the primary members of the LACUC are available, the alternates are considered to be “*ad hoc*” and do not perform official LACUC actions.
  - F. Complete approval (i.e., having no remaining conditions and/or restrictions resulting from a review and approved by the IO) of the proposed activity MUST occur before any animal may be utilized.
- 7. The LACUC procedures for reviewing proposed changes in ongoing research projects are similar to the procedures outlined in Item III.D.6. Amendments are posted on a secure website for committee access. Members can make comments and have the options to require full committee review at the next monthly meeting. A designated reviewer is assigned by the Chair to review the amendment and either recommend approval, require modification to secure approval, or refer the amendment to full committee review.
  - 8. Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure LACUC approval as set forth in the PHS Policy at IV.C.4. The LACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are:
    - a. The Office of Research and Sponsored Program (RSP), in conjunction with the LACUC Chair and veterinarian, notifies in writing the affected investigators of the LACUC initial review decision(s). Once recommended for approval, both the LACUC Chair and the Institutional Official sign the approval notification.
    - b. All such correspondence shall include any required modifications needed to secure approval or any reasons for protocol deferral or action withheld and giving investigators the opportunity to respond in person or in writing.
  - 9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the LACUC, including a complete review in accordance with the PHS Policy at IV.C.1-4. at least once every three years. The LACUC procedures for conducting continuing review are:
    - a. Continuing reviews are conducted at twelve (12) month intervals by designated member review. Investigators are notified by RSP in writing prior to the expiration date and requested to submit an online questionnaire and summary of the previous period’s activities.
    - b. With the exceptions noted below, continuing reviews will be conducted by two (2) committee members; a Veterinarian and the LACUC Chair. Unless full Committee review is requested by either designated reviewer or a member of the LACUC,

notification of review outcome is provided to the LACUC *via* the following month's agenda and minutes.

- c. All correspondence regarding continuing reviews shall be handled by RSP as previously described (Item III.D.8.).
  - d. Each Animal Use Protocol (AUP) shall be unique and shall be active for a maximum period of three (3) years, unless closure is requested by the P.I. At the end of this three-year period, 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. Review and approval of the new animal use protocol must go through the full committee review process as stipulated above. A complete *de novo* review of all activities must be conducted by the full committee review process.
10. The LACUC is authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6. The LACUC procedures for suspending an ongoing activity are as follows:
- a. The LACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the LACUC being present. A majority vote is required and a minority opinion shall be allowed for opposing view point(s). If a suspension is authorized, all activity will immediately cease.
  - b. If circumstances involving animal health, safety, and/or welfare dictate, the Veterinarian, a subcommittee of the LACUC, or the Institutional Official may temporarily stop an activity. Supporting evidence shall be reviewed by the full LACUC as in Item a. above to determine the action of the LACUC.
  - c. All affected parties including, but not limited to, the investigator, the Institutional Official, and the appropriate oversight (e.g., Federal) agencies, shall be notified of the reasons for the suspension, any applicable corrective action(s) and any further action(s) anticipated. If the LACUC suspends an activity involving animals, the Institutional Official, in consultation with the LACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW.

E. The risk-based Occupational Health and Safety Program for personnel working in laboratory animal facilities and personnel who have frequent contact with animals is as follows:

- 1. The Environmental Health and Safety (EHS) Office administers the Occupational Health and Safety Program in conjunction with an Occupational Health Physician.
- 2. The Program is based on Risk Assessment and Hazard Identification. In consultation with the Occupational Health Physician, a matrix depicts job category, the zoonotic hazards associated with animals in the field or in research, the prophylactic medical treatment required, and frequency of medical treatment or examinations. EHS also provides Personal Protective Equipment (PPE) assessments, the industrial hygiene monitoring and related EHS training.

3. Tetanus vaccination and prophylaxis are offered to employees.

4. A Health Evaluation is utilized. In consultation with the Occupational Health Physician, a matrix depicts job category, the zoonotic hazards associated with animals in the field or in research, the prophylactic medical treatment required, and frequency of medical treatment or examinations.

5. The Wright State University Occupational Health and Safety Program applies to designated visitors, students, faculty, and staff who work at the University or in University-managed facilities. Enrollment in the program is required for all individuals 1) working in the LAR; 2) having direct contact with animals; 3) having direct contact with non-sanitized animal cages or enclosures; 4) having direct contact with non-fixed or non-sterilized animal tissues, fluids, and/or wastes; or 5) providing service or support to animal equipment, devices and/or facilities.

To gain access to the LAR, personnel must complete a questionnaire at the conclusion of the on-line Occupational Health and Safety training. Training targets researchers and support personnel. The support personnel receive classroom instruction in hazard communication, signs, labeling, PPE, accident reporting and emergencies, and medical surveillance.

6. EHS maintains written programs for personal hygiene, handling hazardous agents and personnel protection. The online Occupational Health and Safety training program addresses zoonoses, allergens, non-human primates, medical surveillance, PPE, personal hygiene, hazard communication, and accident reporting.

7. Specific training is provided in the areas of zoonosis, allergies, and hazards, and is required to be taken before access to the LAR is authorized. In addition, a 1.5 hour introductory lecture presented by the WSU clinical veterinarian is required to be taken before access to the LAR is allowed.

8. The health and safety policies of Wright State University are described at <http://www.wright.edu/wrightway/#6000>. Employees are advised prior to working with animals of the risks of individuals who are pregnant or have decreased immune-competence of the potential hazards. They are advised that should they have such conditions to consult with the Occupational Health Physician.

9. In the event of bites, scratches, illness or injury, treatment is provided by the Occupational Health Physician. If he is not available the individuals go to one of the local hospitals for emergency care. There is a reporting structure for injuries.

10. All personnel with non-human primate contact are required to complete all aspects of the online Occupational Health and Safety training program.. Non-human primate safety procedures are described in the LAR accidents and emergencies Standard Operating Procedures in addition to the EHS occupational health matrix. Personnel are tested for TB, made aware of the risks of herpes B, are vaccinated for measles (if not done previously), and are informed of the SOP for treatment of bites, and scratches.

F. The total gross number of net assignable square feet (nasf) in each facility/area is given on page 1, item I and in Attachment 3 of these assurances.

The animals utilized and the average daily inventories of each for July 1, 2011 through June 30, 2012 are also given in Attachment 3 of these assurances.

- G. As part of this Institution's program for animal care and use, all personnel involved in animal use activities (investigators, technicians and animal care personnel) are required to participate in a training program prior to any animal use. All personnel using animals must complete the training program offered by Laboratory Animal Resources. Personnel requiring immediate approval for animal use may complete an on-line course and test offered through the Collaborative Institutional Training Initiative (CITI) at <http://www.citiprogram.org/> and receive immediate access, but must still complete the course offered by Laboratory Animal Resources within six months. The training course offered by the Laboratory Animal Resources is modeled after the core program delineated in Education and Training in the Use of Laboratory Animals: A Guide for Developing Institutional Programs, National Academy Press, Washington, D.C., 1991, and includes a combination of lecture and written reference information. The topics covered include:
1. familiarization with the intent and requirements of the Animal Welfare Act, Animal Welfare Regulations, Public Health Service Policy on the Humane Care and Use of Laboratory Animals, the *Guide for the Care and Use of Laboratory Animals*, and other applicable regulations and guidelines;
  2. an overview of the various methods of monitoring compliance including those used by the United States Department of Agriculture, the OLAW, and Wright State University, and the potential penalties imposed by each organization;
  3. a description of the responsibilities of the University, the Laboratory Animal Care and Use Committee, the University Veterinarian, the Laboratory Animal Resources staff, and the research staff;
  4. a discussion of the ethical and scientific issues involved with the use of laboratory animals in research, education, and testing including various ethical approaches and responsibilities and the responsibility of providing proper animal care and husbandry for valid research results;
  5. humane methods of animal maintenance and experimentation including methods that will minimize or eliminate the use of animals, or limit or minimize animal pain or distress;
  6. a presentation of available resources that should be used to identify potential alternatives to animal use or duplication of research, educational, or testing procedures including the National Library of Medicine, the National Agricultural Library, the University Library resources, and internet resources;
  7. a discussion of animal pain and distress including the responsibilities of all involved to minimize pain and distress and the various methods by which pain and distress can be minimized;
  8. a description of the proper use of tranquilizers, analgesics, anesthetics, and paralytics including responsibilities for monitoring effectiveness and animal health and sources for assistance and guidance;

9. proper pre- and post-surgical care including monitoring, the use of analgesics, and where to obtain guidance and assistance;
10. proper aseptic surgical procedures and methods including acceptable surgical locations for various species, requirements for aseptic surgery, responsibilities of all involved, and where to obtain assistance and guidance;
11. methods of euthanasia and requirements for appropriate training;
12. a discussion of potential human health hazards including zoonosis, animal inflicted injuries, and allergies along with a description of the available occupational health program for all personnel with animal contact;
13. an emphasis on each individual's responsibility to ensure humane animal care and use and the methods and individuals available for reporting perceived deficiencies in animal care and treatment.

Additional instruction on the use of specific species, proper anesthetic/analgesic techniques, surgery, etc., is provided in small groups to personnel whose research involves the specific activities. Additional individual training or small group laboratory training is provided by the Laboratory Animal Resources in specific cases where specific techniques and/or new procedures are proposed. Training may also be supplemented from on-line instructional programs from the Collaborative Institutional Training Initiative (CITI) at <http://www.citiprogram.org/>.

In addition to the above, the Institution provides extensive opportunities for personnel involved directly in animal care to attend animal care related meetings. Animal care technicians are encouraged to attend local, regional and national meetings of the American Association for Laboratory Animal Sciences. Members of the LACUC are encouraged and funded to attend various workshops on animal care and use provided by other Institutions, organizations, and the OLAW.

#### IV. Institutional Program Evaluation and Accreditation

As specified in the PHS Policy at IV.A.2., as Category 1, all of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated and accredited by The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have also been evaluated by the LACUC and will be reevaluated by the LACUC at least once every six (6) months, in accord with IV.B.1. and 2. of the PHS Policy, and reports prepared in accord with IV.B.3. of the PHS Policy.

All LACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the Guide. Any departures from the Guide will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the LACUC evaluations will be submitted to the Vice President for Research and Graduate Studies. Semiannual reports of LACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

## V. Recordkeeping

- A. This Institution will maintain for at least three years:
  - 1. A copy of this Assurance and any modifications thereto, as approved by the PHS.
  - 2. Minutes of LACUC meetings, including records of attendance, activities of the committee, and committee deliberations.
  - 3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether LACUC approval was granted or withheld.
  - 4. Records of semiannual LACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, the Vice President for Research and Graduate Studies.
  - 5. Records of accrediting body determinations.
- B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the LACUC for the duration of the activity and for an additional three years after completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

## VI. Reporting Requirements

- A. This Institution's reporting period is January 1 through December 31. The LACUC, through the Institutional Official, will submit an annual report to OLAW before January 31<sup>st</sup> of each year. The report will include:
  - 1. Any change in the accreditation status of the Institution (e.g., if the Institution's AAALAC or AAALAC accreditation is revoked);
  - 2. Any change in the description of the Institution's program for animal care and use as described in this Assurance;
  - 3. Any change in the LACUC membership.
  - 4. Notification of the dates that the LACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, the Vice President for Research and Graduate Studies.
  - 5. Any minority views filed by members of the LACUC.
- B. The LACUC, through the Institutional Official, will promptly provide OLAW 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 suspension of an activity by the LACUC.
- C. Reports filed under VI.A. and VI.B. above shall include any minority views filed by members of the LACUC.