# KANSAS STATE UNIVERSITY

# ASSURANCE OF COMPLIANCE WITH PUBLIC HEALTH SERVICE POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS

Kansas 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 the PHS Policy.

### I. I. APPLICABILITY

This Assurance is applicable to all research, research training, experimentation, biologic 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 subcontracting or subgranting of a PHS-conducted or supported activity by this institution.

"Institution" includes the following branches and major components of Kansas State University: Colleges of Agriculture, Arts and Sciences, Engineering, Human Ecology, and Veterinary Medicine.

- II. II. INSTITUTION POLICY
  - A. A. This institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
  - B. 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. C. This 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 make a reasonable effort to 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 other applicable laws and regulations pertaining to animal care and use.
  - D. 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. (Guide).

# III. III. INSTITUTIONAL PROGRAM FOR ANIMAL CARE AND USE

A. A. The lines of authority and responsibility for administering the program and ensuring compliance with this Policy are:

President Kansas State University:	Dr. John Wefald, Ph.D.	
Provost, Kansas State University:	Dr. James Coffman, DVM, MS	
Vice Provost for Research and		
Dean of the Graduate School, and		
Institutional Official (IO):	R.W. Trewyn, Ph.D.	
Associate Vice Provost for Research Compliance	-	
and University Veterinarian:	Jerry Jaax, DVM, ACLAM	
Institutional Animal Care and Use Committee (IACUC)		
Attending Veterinarian and Director		
of the Animal Resources Facility, CVM	Bart Carter, DVM	

\* Schematic attached – Attachment 1

The Institutional Official (IO) is R.W. Trewyn, the KSU Vice Provost for Research, and the Dean of the Graduate School. He reports to the Provost, who in turn reports to the President of the University. The University Veterinarian is Jerry Jaax. He is also the Associate Vice Provost for Research Compliance with

oversight responsibility for all animal care and use on campus, human subjects research, and biosafety. Dr. Jaax reports directly to Dr. Trewyn, the IO. The University Research Compliance Office (URCO) provides administrative support for the animal care and use program, and the Institutional Animal Care and Use Committee (IACUC).

The Chair of the IACUC is Dr. Janice Swanson, Associate Professor in the Department of Animal Science and Industry. The Chair is appointed by the IO. Each person in the described line of authority maintains an open door policy for comments or concerns about campus-wide animal care and use.

B. B. The qualifications, authority, and percent time contributed by the veterinarians\*\* who participate in the program are:

#### Institutional Veterinarian: Jerry Jaax

Experience: Dr. Jaax received his DVM from KSU in 1972. After a formal residency program in laboratory animal medicine at USAMRIID, Ft. Detrick MD, he became a Diplomate of the American College of Laboratory Animal Medicine (ACLAM) in 1984. Dr. Jaax served in a number of leadership positions pertaining to animal care and use while in the military, to include the "Consultant to the Surgeon General of the Army" for the specialty of Laboratory Animal Medicine, program director for a post-graduate training program in Laboratory Animal Medicine at both Ft. Detrick, and Aberdeen Proving Ground, MD, and as an Adjunct Faculty member in the Department of Preventive Medicine and Biometrics at the Uniformed Services University of the Health Sciences (USUHS) in Bethesda MD. He is currently an *ad hoc* consultant for AAALAC and has a faculty appointment in the Department of Diagnostic Medicine and Pathobiology (DMP) at the KSU College of Veterinary Medicine. Dr. Jaax has over 22 years of experience in animal care and use and laboratory animal medicine.

Program Authority: Dr. Jaax has programmatic responsibility for the animal care and use program, and provides administrative support for the IACUC. Holding an appointment in the central research administration, Dr. Jaax is able to interface effectively with researchers, educators, and administrators across college and department boundaries. He receives strong support from IO and the central administration on animal care and use issues.

Time Commitment: Dr. Jaax is a full time employee of the institution. On average, he spends approximately 55-60% of his time on animal care and use issues at the institution.

#### Attending Veterinarian: Bart Carter

Experience: Dr. Carter is the Director of the Animal Resource Facility (ARF) in the College of Veterinary Medicine (CVM). The ARF is the central animal facility for the CVM located in Coles Hall. Dr. Carter received his DVM from University of Missouri in 1990. He currently supervises all animal based research programs within the university and assists in the writing of animal use protocols and grant proposals. Dr. Carter also ensures compliance with USDA regulations as well as PHS policy and AAALAC accreditation standards.

Program Authority: Dr. Carter is the Attending Veterinarian for the animal care and use program. As such, he exercises the full campus authority of the attending veterinarian under animal welfare laws, guidelines, and regulations.

Time Commitment: Dr. Carter devotes 100% time to the animal care and use program.

\*\* The institution is a land grant university with a college of Agriculture and a College of Veterinary Medicine. Consequently, there are many veterinarians in addition to the university veterinarian and the attending veterinarian who directly and indirectly contribute to the animal care and use program, either through service on the IACUC, as researchers, or in expert, clinical or technical support roles.

C. C. This institution has established an Institutional Animal Care and Use Committee (IACUC), which is qualified through the experience and expertise of its members to oversee the institution's animal care and use program, facilities, and procedures. The IACUC consists of at least five members, and its membership meets the composition requirements set forth in the PHS Policy at IV.A.3.b. Attached is a list of names, degrees, position titles, specialties, and institutional affiliations of the IACUC chairperson and members (Attachment 2). Neither of the non-affiliated IACUC members are animal users. Their primary charge from the committee is to represent the general community interests.

### D. D. The IACUC will:

1. Review at least once every six months the institution's program for humane care and use of animals, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual program evaluations are: Semi annual program evaluations are conducted on the 2<sup>nd</sup> or 3<sup>rd</sup> week of April, and on the 2<sup>nd</sup> or 3<sup>rd</sup> week of October each year. The dates of the evaluation are scheduled six months apart in accordance with regulatory guidance. The IACUC performs its formal program review using "The Guide," and a review instrument adapted from the online checklist the OLAW semiannual review on website http://grants.nih.gov/grants/olaw/sampledoc/cheklist.htm. Deficiencies noted during the review are categorized as either significant (deemed to be a threat to the health or welfare of the animal) or minor. A plan and schedule for resolution of deficiencies is prepared and included in formal correspondence from the IACUC to the responsible individual. Final findings, recommendations and actions are reviewed, discussed, and voted upon in a convened full committee meeting. All members of the IACUC sign and date the final report to the IO. There is a provision for minority opinion on the signature sheet accompanying the final report to the IO.

2. 2. Inspect at least once every six months the institution's animal facilities, including satellite facilities, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual facilities inspections are: semiannual facilities inspections are conducted on the  $2^{nd}$  and  $3^{rd}$  week of April and on the  $2^{nd}$  or  $3^{rd}$  week of October of each year. The dates of the inspection are scheduled six months apart IAW regulatory guidance. All institutional animal care and use facilities are inspected, regardless of accreditation or PHS Assurance status. The IACUC performs its formal facilities inspection using "The Guide," and a review instrument adapted from the online semiannual inspection checklist on the OLAW website http://grants.nih.gov/grants/olaw/sampledoc/cheklist.htm. Since the actual facilities inspection typically takes approximately four days, the IACUC often uses subcommittees to help accomplish this task. Final findings, recommendations and actions are reviewed, discussed, and voted upon in a convened full committee meeting. All members of the IACUC sign and date the final report to the IO. There is a provision for minority opinion on the signature sheet accompanying the final report to the IO.

Attending Veterinary Care Surveillance Program: The IACUC has implemented a formal program of surveillance of attending veterinary care for facilities using animals in teaching, research, or testing. In addition to the attending veterinarian, the IACUC has designated AALAS certified veterinary technicians as adjunct agents of the IACUC. They perform unannounced attending care assistance visits to animal care and use facilities across campus.

During attending care visits, they monitor research animal health and well being, husbandry, sanitation, and other pertinent aspects of animal care and use, to include IACUC protocol compliance. Additionally, they assist personnel with animal care and use issues, procedures, and training, etc. The frequency of visits to individual animal care and use areas is based on animal use activity and need, but occur at least once a month. The University Research Compliance Office (URCO) maintains documentation of the attending care visits. If significant issues or problems are identified during visits, the attending veterinarian and/or university veterinarian perform appropriate follow-up actions. If warranted, the university veterinarian and/or attending veterinarian refer significant findings to the IACUC, or the Institutional Official (IO) for additional consideration and/or formal action.

3. 3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy at IV.B.3., and submit the reports to R.W. Trewyn, the Institutional Official. The IACUC process for developing the report and submitting to the IO is: The semiannual evaluations are performed as scheduled for all aspects of the program, and all animal facilities in the unit. Findings, deficiencies, recommendations and proposed actions are reviewed, discussed, and voted upon in full committee. Deficiencies noted during the review are categorized as either significant (deemed to be a threat to the health or welfare of the animal) or minor. A plan and schedule for resolution of deficiencies is prepared and included in formal correspondence from the IACUC to each responsible individual. The results of the program evaluation, along with specific findings and

- recommendations, and/or actions are forwarded to the Institutional Official for information, and if appropriate, further action. The IO reviews and signs the final semiannual report of program and facilities.
- 4. 4. Review concerns involving the care and use of animals in the institution. The IACUC procedures for reviewing concerns are: The animal care and use program home page <a href="http://www.ksu.edu/research/animal/index.htm">http://www.ksu.edu/research/animal/index.htm</a>. has a site with pertinent information and procedures for any person who desires to register a concern or a complaint about animal care and use at the institution. <a href="http://www.ksu.edu/research/animal/iacuc/index.htm">http://www.ksu.edu/research/animal/iacuc/index.htm</a>. It explains the rights of any individual to express concerns, and reaffirms that any concern will be treated confidentially, or anonymously, if desired. The names, and contact information to include e-mail, for key individuals is provided on the site. In addition, the IACUC has prepared colorful signs that are prominently posted in all areas used in the animal care and use program. This sign also contains all pertinent information about how, and to whom to register a concern or complaint about animal care and use in the institution. The sign also explains that concerns or complaints can be made anonymously, and with no fear of reprisal.

Upon receipt of a concern or complaint, the IACUC initiates a formal investigation. This may be performed initially by a designated subcommittee of the IACUC, usually including the university veterinarian, the attending veterinarian, and the Chair. The findings of the investigation are presented and discussed in the full committee. When a concern or complaint is received by the IACUC, the IO is informed immediately. Once the issue has been properly investigated by the IACUC, the IO is informed in writing of the full findings and results. The IO may then take whatever action is deemed appropriate, to include notification of the Office of Laboratory Animal Welfare (OLAW) with a full explanation of the issues and actions.

The IACUC has its Administrative Operating Procedures (AOP) posted on the animal care and use homepage <u>http://www.ksu.edu/research/animal/iacuc/index.htm</u>. IACUC procedures for investigating concerns or complaints are outlined in the AOP.

5. 5. Make recommendations to Dr. R.W. Trewyn, the IO, regarding any aspect of the institution's animal program, facilities, and personnel training. The procedures for making recommendations to the IO are: As described in III.D.2., and III.D.3. above, the IACUC presents the IO with a formal semiannual report of the program and facilities. Dr. Trewyn reviews the report and takes any action deemed appropriate as a result of the IACUC inspection and/or review. As other unanticipated or non-routine issues appropriate for notification arise, they are brought to the attention of the IO.

Since the IO is the direct line supervisor and is daily contact with the university veterinarian (Dr. Jaax), he has immediate access to information about all pertinent issues regarding the animal care and use program.

- 6. 6. 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. The IACUC procedures for protocol review are:
  - IACUC Procedures for review and approval: The animal care and use program home page has an online IACUC Application for Approval document in standard word processing formats. <a href="http://www.ksu.edu/research/animal/iacuc/index.htm">http://www.ksu.edu/research/animal/iacuc/index.htm</a>. The principal investigator (PI) downloads the template, completes the application, and forwards the application proposal to the University Research Compliance Office (URCO). The URCO logs in the application in a comprehensive Access database, and forwards the proposal to all members of the committee. All members review the proposal with a primary eye to determining whether a convened "full" committee review, or a formal "designated" review is appropriate. Only proposals that are Category 1, defined as no, or slight or temporary pain and/or distress are eligible for designated review. During initial review, any member can request full committee review for any proposal, even those in Category 1. Requesting a full committee review requires no explanation or justification from the requestor.
    - Designated Review: (Category 1 proposals only). If members unanimously recommend designated review, the URCO selects a member to review the proposal. Stipulations are forwarded to the PI, who must respond to them in a satisfactory manner.

- Once the proposal has been adequately reviewed and a recommendation made, the Chair approves, or disapproves the proposal. The results of all designated reviews are recorded in the minutes of a convened full committee. A flow chart graphically describing the designated review process is provided at Attachment 3.
- Full Committee Review: {All Category 2 proposals (alleviated pain and/or distress), all Category 3 proposals (unalleviated pain and/or distress), or those Category 1 proposals that a member requested a full committee review}. The IACUC meets twice a month. The Chair directs the meeting with a quorum being necessary for reviewing proposals. PI's with proposals are invited to the meeting, provide a brief oral overview of the proposal, and answer questions in turn from each of the members. Following the questions and/or clarifications, the PI (and any committee member with a potential conflict of interest) is excused and general committee discussion ensues. A voice vote, and if necessary for approval of a proposed activity. Committee deliberations and voting usually results in approval with a varying number of stipulations, although occasionally a proposal is disapproved outright. In-committee review typically lasts from 15-30 minutes per proposal, with exceptions on both ends of the scale.

Following full committee review, the PI is notified in writing of the results of the deliberations of the committee. He/she must respond to stipulations to the satisfaction of the committee. Once this is done, the Chair approves the proposal, the PI is notified in writing and is authorized to proceed with the protocol. The approval period lasts for a maximum of three years, or until the approved activity is completed in the manner described in the protocol, which ever comes first. All activities are reviewed on at least an annual basis. Conversely, if the proposal is disapproved, the PI is notified in writing of the decision and the basis and/or rationale for the decision of the committee.

Even though IACUC approval of a proposed activity may be subject to further review at the institution, the decision of the IACUC to disapprove or withhold approval for a specific animal care and use activity cannot be overruled by other administrative elements at the institution.

7. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy at IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research are: The IACUC has Administrative Operating Procedures (AOP) posted on the animal care and use homepage http://www.ksu.edu/research/animal/iacuc/index.htm. Procedures for approval of proposed significant changes and in ongoing research as described in the AOP follow.

III.G. Changes to Protocols/Activities: The Chair will make the determination whether a proposed change to an activity or protocol is minor or significant. Regardless of the determination and level of review by the Chair, all approved changes or modifications will be recorded in the minutes at a full committee meeting for documentation, and discussion if appropriate. The PI is notified in writing of the formal approval/disapproval of their proposed change or modification. No proposed change or modification in an approved ongoing animal care and use activity can commence prior to formal approval of the proposed change.

- Significant Modifications/addenda: If determined by the Chair that the proposed change (s) to ongoing activities is a major change, the P.I. must complete a new protocol application, completing the sections of the application for approval pertinent to the proposed changes. The Chair will make a determination whether the proposed change will be reviewed in full committee, subcommittee, or can be approved by the Chair.
- Minor Modifications/addenda: Upon determination by the Chair that a proposed modification is indeed a minor change, the P.I. may submit a memo to the IACUC describing in detail the proposed minor modification/addenda. If adequately presented and justified by the P.I., a minor modification/addenda may be approved by the Chair.
- 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 IACUC approval as set forth in the PHS Policy at IV.C.4. The IACUC procedures to notify investigators and the institution of its decisions regarding protocol review are: as described

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- in III.D.6. above all formal activity, decisions and actions of the committee are documented in writing. Investigators are notified in writing as soon as possible of the results of the deliberations and decisions of the committee. If desired, the PI may respond to the committee in writing, or appear at a meeting of the IACUC to discuss or receive clarification of the actions of the committee. All committee correspondence is maintained by the University Research Compliance Office for reference and examination by authorized regulatory oversight and accrediting bodies.
- 9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at IV.C.1-4 at least once every three years. The IACUC procedures for conducting continuing review are:
  - Protocol Approval Period: Protocols are approved for up to three years. If the ongoing activity is going to exceed the three year IACUC approval window, the PI must submit a new application for approval (http://www.ksu.edu/research/animal/iacuc/index.htm.) with all pertinent data required by the committee for any new proposed animal care and use activity. The application for approval for an ongoing activity that will soon exceed the three year window of approval is managed and reviewed by the committee in the same manner as any new proposal.
  - Continuing Review of Protocols: The access database maintained by the University Research Compliance Office (URCO) is the primary tool used to flag ongoing animal care and use activities for continuing review. This ongoing review is accomplished on at least an annual basis. The URCO contacts the PI three months prior to the yearly anniversary of the approval date of the protocol. The PI must complete a standardized form that questions key aspects of the activity. The PI responds to the questions on the review form, and sends it back to the URCO. If the protocol is proceeding in accordance with the provisions of the original approval and any IACUC approved changes or modifications, the activity may continue with no further action by the IACUC or URCO. If the continuing review reveals that additional oversight or review by the URCO or the committee is required, the appropriate actions are initiated.
- 10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6. The IACUC procedures for an ongoing activity are: The IACUC Administrating Operating Procedures (AOP) section III.G. states that "The IACUC may suspend a previously approved activity involving animals if it determines that the activity is not being conducted in accordance with applicable provisions of animal welfare laws, regulations and guidelines. The IACUC may suspend an activity only after investigation and review of the matter at a convened meeting of a quorum of the IACUC, and a suspension vote by a majority of the quorum present. If the IACUC suspends an activity, the Institutional Official in consultation with the IACUC shall review the reasons for the suspension, take appropriate corrective action, and report that action with a full explanation to appropriate regulatory and oversight bodies."
- E. E. The individuals authorized by this institution to verify IACUC approval of those sections of applications and proposals related to the care and use of animals are
  - • Bart Carter– IACUC Chair
  - Steve Upton IACUC Vice Chair
  - Jerry Jaax University Veterinarian, University Research Compliance Officer, IACUC member
- F. F. The Occupational Health and Safety Program (OH&SP) for personnel who work in laboratory animal facilities or have frequent contact with animals is: administered out of the University Research Compliance Office (UCO). A significant amount of information about the OH&SP and other related matters available workers online is for animal or researchers at http://www.ksu.edu/research/animal/occhs/index.htm. The OH&S program pertains to all occupational animal workers and/or personnel working with animals in research or teaching at the institution. A concise overview of the program that is sent to eligible personnel is provided at Attachment 4. Key elements of the OH&SP program are described below:
  - This program consists of a required assessment of health history, follow-on diagnostic tests and immunizations (if required), and a possible physical examination (if required). All personnel with occupational contact with animals in research, testing, or teaching must complete an Animal Worker Questionnaire (provided as Attachment 5). The questionnaire is reviewed by a physician who assesses risk and makes appropriate recommendations. Recommendations usually consist of requesting

additional information, diagnostic testing, vaccinations, or clearance to work with animals. The animal worker is notified in writing of the results and recommendations of the physicians review of the questionnaire.

- Any person at the institution working with animals in an occupational way, such as animal care takers, herdsmen, student workers, etc.; or researchers, graduate students, or students having contact with animals in research or teaching activities are required to enroll in the OH&S program. The IACUC application form has a section where PI's list all protocol-associated personnel. This is used to identify personnel for both animal care and use training and enrollment in the OH&SP.
- Based on species contact information in the questionnaire, the URCO sends each animal worker a tailored packet of "fact sheets" targeting potential risks for that individual. These fact sheets provide specific information including but not limited to hygiene, allergies, immunosuppression, sharps, pre-exposure rabies prophylaxis, respiratory hazards, and common zoonotic diseases, etc., and are available online at <a href="http://www.ksu.edu/research/animal/occhs/index.htm">http://www.ksu.edu/research/animal/occhs/index.htm</a>.
- • There is no automatic pre-employment physical required for animal care personnel.
- • The animal worker questionnaires are reviewed by a physician (Dr. Reppert) at the university health clinic, who evaluates potential risks associated with the activity using animals. He makes professional recommendations based on the information in the questionnaire provided by the animal worker. Dr. Reppert is also a voting member of the Institutional Biosafety Committee (IBC) and the institution's Environmental Health and Safety Committee.
- Institutional employees have a standard procedure to follow if they are injured while working. They are required to report to a local hospital, if appropriate, and to complete a standard institutional form describing and documenting the injury. The OH&SP fact sheets also address the issue of animal-related injury.
- The Institutional Biosafety Committee (IBC) has responsibility for oversight and review of any proposed activity using recombinant DNA molecules or infectious agents. The IBC must approve these activities prior to initiation of those new activities. The IBC homepage is available online at http://www.ksu.edu/research/ibc/index.htm. Personnel using infectious agents or recombinant DNA molecules are required to complete online training for those activities prior to initiation of that activity. Animal use with rDNA and infectious agents is addressed in the IBC training modules. There are no current institutional activities using infectious agents classified above the CDC's Biosafety Level Two (BL-2) category.
- The institution has an Environmental Health and Safety Department, and an Environmental Health and Safety Committee that addresses many of the other common laboratory hazards and safety issues such as radiation protection, chemical hygiene, respiratory protection, laboratory safety, fire prevention, etc. Their online homepage is available at <a href="http://www.ksu.edu/research/animal/occhs/index.htm">http://www.ksu.edu/research/animal/occhs/index.htm</a>.
- • The institution currently has no nonhuman primates in its animal care and use program, and has no plans to use them.
- • All personnel working with animals must have a current tetanus vaccination (within 10 years).
- G. G. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein and the average daily inventory of animals by species, in each facility is provided in the attached table (Attachment 6).
- H. H. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is: The IACUC application for approval form has a section that addresses training for personnel involved in animal care and use. The IACUC considers documentation of adequate training as part of its review of animal care and use proposals. Specific aspects of the training program are as follows:
  - Online Training: An online training program has been implemented for the animal care and use program. The training is targeted for all institutional personnel who are involved in the use of animals in research, teaching or training. An IACUC proposal to use animals in research, testing, or teaching will not be approved prior to documentation of completion of each required training module by all personnel associated with the proposed activity. Based on species and procedure, the URCO will verify that personnel complete the required training modules. Documentation of training is maintained in the URCO access database. Re-training will be required every three years at a minimum.
    - Overview of Animal Care and Use: This basic introductory module is required for all institutional personnel involved in animal care and use. It addresses but is not limited to topics

- such as: history of animal experimentation; animal use laws, regulations and policies; overview of the animal welfare movement, animal use alternatives, various reference services, reporting of deficiencies, concerns, or complaints about animal use, ethical considerations, the PHS Policy, "The Guide," occupational health information, compliance requirements, humane endpoints, IACUC functions, general euthanasia issues, surgical considerations, etc.
- Species Specific Training Modules: Each commonly used species in the animal care and use program, such as rats, mice, guinea pigs, dogs, cats, etc., has a required training module. These individual modules address species specific issues, such as: animal use history, basic needs and husbandry, handling, identification, procurement, specific requirements under the CFR or other regulatory drivers, nutrition, behavior, anesthesia/analgesia, surgery considerations, applicable diseases, euthanasia, biosampling sites, etc.
- Procedure Specific Training: modules are being developed for specific animal care and use procedures, such as: aseptic surgery techniques for rodents, etc.
- • The institutional training modules can be accessed online at <u>http://www.ksu.edu/research/animal/training/index.htm</u>.
- Audio-visual Materials: The Animal Resource Facility (ARF) at the College of Veterinary Medicine, and the Laboratory Animal Care Service (LACS) in the Department of Biology, College of Arts and Sciences have amassed a significant library of audio visual animal care and use training materials. Investigators are encouraged to utilize the materials as appropriate to supplement their listing of the extensive training materials library training. А is at http://www.ksu.edu/research/animal/training/index.htm.
- • Hands-on Training: As necessary, individual investigators are trained on animal care and use procedures by the attending veterinarian, or other appropriate subject matter expert. Examples could include aseptic surgical procedures, handling and restraint, venipuncture techniques, etc.
- AALAS Technician Certification: The institution has emphasized certification training for personnel involved in the animal care and use program. There are three animal care and use personnel certified at the Assistant Laboratory Animal Technicians (ALAT), and two technicians certified at the Laboratory Animal Technician (LAT) level. This contrasts with no AALAS certified technicians in the animal care and use program as recently as three years ago.
- Institutional Biosafety Committee (IBC) Online Training Program: The IBC has a mandatory training program for those using infectious agents and/or recombinant DNA molecules. Personnel are required to complete online training for those activities prior to initiation of that activity. Many issues pertinent to animal care and use are addressed in the IBC training modules.

#### IV. IV. INSTITUTIONAL STATUS

As specified in the PHS Policy at IV.A.2., as Category 2, <u>all</u> of this institution's programs and facilities, including satellite facilities, for activities involving animals have been evaluated by the IACUC and will be reevaluated by the IACUC at least once every six 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 IACUC semiannual reports will include a description of the nature and extent of this institution's adherence to the <u>Guide</u>. Any departures from the <u>Guide</u> will be identified specifically, and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facilities deficiencies are noted, reports will contain a reasonable and a specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC evaluations will be submitted to Dr. R.W. Trewyn, the Institutional Official (IO). Semiannual reports of the IACUC evaluations will be maintained by this institution and be made available to the Office of Laboratory Animal Welfare (OLAW) upon request. The most recent semiannual report of the IACUC is provided at Attachment 7.

### V. V. RECORD KEEPING REQUIREMENTS

- A. A. This institution will maintain for at least three years:
  - 1. 1. A copy of this assurance and any modifications thereto, as approved by the PHS.
  - 2. 2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations.
  - 3. 3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld.
  - 4. 4. Records of semiannual IACUC reports and recommendations (including

minority views) as forwarded to Dr. R.W. Trewyn, the IO.

- B. B. This institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after the completion of the activity.
- C. 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. VI. REPORTING REQUIREMENTS

- A. A. At least once every 12 months, the IACUC through the institutional official will report in writing to OLAW:
  - 1. 1. Any change in the status of the institution (e.g., if the institution becomes accredited by AAALAC or AAALAC accreditation is revoked), any change in the description of the institution's program for animal care and use as described in this Assurance, or any changes in the IACUC membership. If there are no changes to report, this institution will provide OLAW with written notification that that there are no changes.
  - 2. 2. Notification of the dates that the IACUC conducted its semiannual evaluations of the institution's program and facilities (including satellite facilities) and submitted the evaluations to Dr. R.W. Trewyn, the IO.
- B. B. The IACUC, through the Institutional Official, will provide the OLAW promptly with a full explanation of the circumstances and actions taken with respect to:
  - 1. 1. Any serious or continuing noncompliance with the PHS Policy
  - 2. 2. Any serious deviations from the provisions of the <u>Guide</u>.
  - 3. 3. Any suspension of an activity by the IACUC.
- C. Reports filed under VI.A. and VI.B. above shall include any minority views filed by members of the IACUC.

# VII. VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A.	А.	Authorized Institutional Official
	Name:	R.W. Trewyn
	Title:	Vice Provost for Research and Dean of the Graduate School
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C.	C.	Effective Date of Assurance:
D.	D.	Expiration Date of Assurance: