ARKANSAS STATE UNIVERSITY A4506-01

ANIMAL WELFARE ASSURANCE in accordance with the PHS Policy for Humane Care and Use of Laboratory Animals

I, Michael E. Dockter, Ph.D., Associate Chancellor for Research, as named Institutional Official for animal care and use at Arkansas State University, hereinafter referred to as Institution, by means of this document, provide assurance that this Institution 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 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 a PHS-conducted or -supported activity by this Institution.

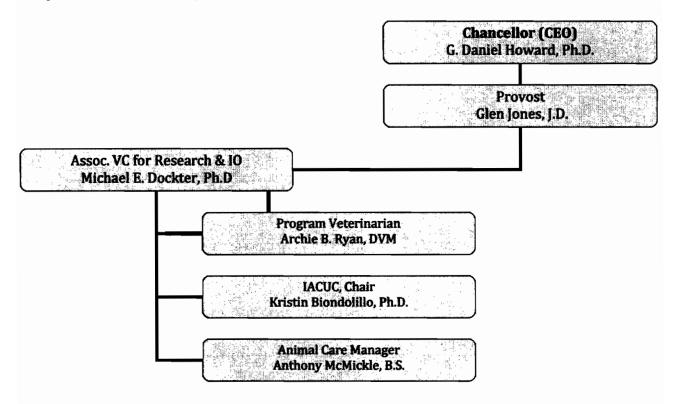
"Institution" includes the following branches and major components of Arkansas State University (ASU): All components of ASU that are physically located on the University's Main Campus in State University, Arkansas, 72467. There are no off-campus satellite facilities and/or other covered components.

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. 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 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" ("Guide").

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 as follows:



Note: As indicated above, there are direct and open lines of communication between the IACUC and the Institutional Official (IO) and between the Veterinarian and the IO.

B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

Name: Archie B. Ryan Qualifications:

- Degrees: D.V.M., Louisiana State University, 1987; Licensed to practice veterinary medicine in Arkansas; Federally-Licensed Migratory Bird Rehabilitator.
- Training and/or experience in laboratory animal medicine Nineteen years of
 experience practicing veterinary medicine. His practice includes small animals,
 exotics, avian and rodent patients. He stays current with C.E. seminars and
 subscriptions to veterinary practice of NA- exotics, AVMA, AVRJ, JAALAS, and Exotic
 journals along with other veterinary books that include lab animal information.

<u>Authority</u>: Dr. Ryan has delegated program authority and responsibility for the Institution's animal care and use program including the authority to implement the PHS Policy and the recommendations of the Guide.

<u>Time Contributed to Program</u>: Dr. Ryan is present at the Institution an average of approximately four (4) hours per month. One-hundred percent of this time is contributed to the animal care and use program. In addition Dr. Ryan contributes on average approximately four hours per month to the program while off-site reviewing protocols and providing consultation on various program related topics.

<u>Provisions for Back-up Veterinary Care</u>: Gary Strickland D.V.M. is on call for any back-up veterinary care which may be required.

Name: Gary Strickland

Qualifications:

- Degrees: D.V.M., Tuskegee University, 1986.
- Training and/or experience in laboratory animal medicine: Dr. Strickland's
 experience includes 24 years as a small animal practitioner in Arkansas. He
 currently serves as a Committee member on the Institutional Biosafety Committee
 and has prior IACUC experience at ASU that included inspection of the original
 animal facility. As a graduate student, Dr. Strickland also had responsibility for
 management of the laboratory animal rooms at ASU which housed mice, rats, and
 rabbits.

<u>Authority/Responsibilities:</u> Dr. Strickland serves as the back-up veterinary for Dr. Ryan. In Dr. Ryan's absence, Dr. Strickland has the authority and responsibility for ensuring adequate veterinary care as well as the authority to implement the PHS Policy and the recommendations of the Guide.

Time Contributed to Program: As needed for back-up/emergency veterinary service.

C. The Institutional Animal Care and Use Committee (IACUC) at this Institution is properly appointed in accordance with the PHS Policy IV.A.3.a and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The Chancellor has delegated to the Institutional Official the authority to appoint the members of the IACUC. In accordance with the Health Research Extension Act of 1985, this delegation of authority is specific and is in writing. The IACUC consists of at least five members, and its membership meets the composition requirements set forth in the PHS Policy, Section IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations (Attachment A).

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 reviews are as follows: The IACUC will meet at least once every six months to review the Institutional Program for Humane Care and Use of Animals. The Committee uses the Guide and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review. To facilitate the evaluation, the Committee will use a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website. The evaluation will include, but not necessarily be limited to, a review of the following: a) IACUC Membership and Functions: b) IACUC Records and Reporting Requirements; c) Husbandry and Veterinary Care (all aspects); d) Personnel Qualifications (Experience and Training); and e) Occupational Health and Safety. In addition, the evaluation will include a review of the Institution's PHS Assurance. If program deficiencies are noted during the review, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel. No member will be involuntarily excluded from participating in any portion of the reviews.

- 2. Inspect at least once every six months all of the Institution's animal facilities, including satellite facilities, using the "Guide" as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows: At least once every six months at least two (2) members of the IACUC will visit all of the institute's facilities where animals are housed or used, i.e., holding areas, animal care support areas, storage areas, procedure areas, and laboratories where animal manipulations are conducted. Equipment used for transporting of the animals is also inspected. The Committee uses the Guide and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review. To facilitate the evaluation, the Committee will use a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website. If deficiencies are noted during the inspection, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel. No member will be involuntarily excluded from participating in any portion of the inspections.
- 3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy IV.B.3 and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows: Individual IACUC members will convey their observations to the IACUC Chairperson, or his or her designee, who, in turn, will draft the reports using the sample OLAW Semiannual Report to the Institutional Official format from the OLAW website. The reports will contain a description of the nature and extent of the institution's adherence to the Guide and the PHS Policy, identify specifically any departures from the provisions of the Guide and the PHS Policy, and state the reasons for each departure. The reports will distinguish significant deficiencies from minor deficiencies. If program or facility deficiencies are noted, the reports will contain a reasonable and specific plan and schedule for correcting each deficiency. If some or all of the institution's facilities are accredited by AAALAC International the report will identify those facilities as such. Copies of the draft reports will be reviewed, revised as appropriate, and approved by the Committee. The final reports will be signed by a majority of the IACUC members and will include any minority opinions. If there are no minority opinions, the reports will reflect such. Following completion of each evaluation, the completed report will be submitted to the Institutional Official in a timely manner—generally within 30 days.
- **4. Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:** Any individual may report concerns to the IO, IACUC Chair, Institutional Veterinarian, or any member of the IACUC. Notices are located in the animal facilities advising individuals how and where to report animal welfare concerns and stating that any individual who, in good faith, reports an animal welfare concern will be protected against reprisals. All reported concerns will be brought to the attention of the full Committee. If necessary the IACUC Chair will convene a meeting to discuss, investigate, and address any reported concern. Reported concerns and all associated IACUC actions will be recorded in the IACUC meeting minutes. The Committee will report such actions to the IO and, as warranted, to OLAW.
- 5. Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

 Recommendations regarding any aspects of the institution's animal program or facilities are discussed and developed by the Committee. The Committee's recommendations are

included in the IACUC Meeting minutes or a report of the IACUC's evaluations or a separate letter. Such documents are reviewed and approved by the Committee and then submitted to the IO.

6. In accord with the PHS Policy IV.C.1-3, the IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of PHSsupported activities related to the care and use of animals. The IACUC procedures for protocol review are as follows: Prior to the review, each IACUC member will be provided with written descriptions of activities (protocols) that involve the care and use of animals and any member of the IACUC may obtain, upon request, full committee review of those protocols. If full-committee review (FCR) is not requested, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, may be assigned to review those protocols and have the authority to approve, require modifications in (to secure approval) or request full committee review of those protocols. Other IACUC members may provide the designated reviewer with comments and/or suggestions for the reviewer's consideration only. That is, concurrence to use the DMR method may not be conditioned. If multiple designated reviewers are used, their decisions must be unanimous; if not, the protocol will be referred for FCR. If FCR is requested, approval of those protocols may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present.

Generally, the FCR method will be used. However, should a situation warrant it, the institution or IACUC may want to use the designated-member review (DMR) method. In such instances the protocol will be distributed to all IACUC members to allow all members the opportunity to call for FCR; records of polling of members to obtain concurrence to use the DMR method, or concurrence by silent assent after a minimum of five (5) working days, and approval of protocols via DMR are maintained and recorded in the minutes of the next convened IACUC meeting.

<u>Required modifications</u>. When the IACUC requires modifications (to secure approval), of a protocol, such modifications are reviewed as follows:

- 1. FCR or DMR following the procedures delineated above.
- 2. DMR if approved unanimously by all members at the meeting at which the required modifications are developed delineated <u>AND</u> if the entire current Committee has previously approved and documented a policy of DMR for required modifications, provided however, that if any member calls for FCR of the modifications, such modifications can only be reviewed and approved by FCR.
- 3. Minor modifications of an administrative nature, i.e., typographical or grammatical errors, required signatures, etc. may be confirmed by IACUC administrative/support personnel.

No member may participate in the IACUC review or approval of a protocol in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum. The IACUC may invite consultants to assist in reviewing complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC unless they are also members of the IACUC.

Note: Any use of telecommunications will be in accordance with NIH Notice NOT-OD-06-052 of March 24th, 2006, entitled <u>Guidance on Use of Telecommunications for IACUC</u> <u>Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals.</u>

In order to approve proposed protocols or proposed significant changes in ongoing protocols, the IACUC will conduct a review of those components related to the care and use of animals and determine that the proposed protocols are in accordance with the PHS Policy. In making this determination, the IACUC will confirm that the protocol will be conducted in accordance with the Animal Welfare Act insofar as it applies to the activity, and that the protocol is consistent with the Guide unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the protocol conforms to the institution's PHS Assurance and meets the following requirements:

- a. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
- b. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
- c. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
- d. The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.
- e. Medical care for animals will be available and provided as necessary by a qualified veterinarian.
- f. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
- g. Methods of euthanasia used will be consistent with the current recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.
- 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 IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows: Review and approval of significant changes are handled in the same manner as new protocols. See Paragraph III.D.6. above.

Examples of changes considered to be significant include, but are not limited to, changes:

- a. in the objectives of a study
- b. from non survival to survival surgery;
- c. resulting in greater discomfort or in a greater degree of invasiveness;
- d. in the species or in approximate number of animals used;
- e. in Principal Investigator;

- f. in anesthetic agent(s) or the use or withholding of analgesics;
- g. in the method of euthanasia; and
- h. in the duration, frequency, or number of procedures performed on an animal
- 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 IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows: Principal Investigators are notified either by e-mail or letter from the IACUC Chairperson. The Institutional Official is notified by receiving a copy of the PI's notification letter and/or a copy of the IACUC meeting minutes.
- 9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy IV.C.1-4 at least once every three years. The IACUC procedures for conducting continuing reviews are as follows: All ongoing activities are monitored continuously by the animal care and use staff and the associated protocols are reviewed by a member or members of the IACUC at least annually. Annual protocol reviews are recorded in the IACUC meeting minutes. The IACUC meeting minutes are reviewed and approved by the Committee.

Protocols are approved for a maximum of 36 months. That is, all protocols expire no later than the three-year anniversary of the initial IACUC review. If activities will continue beyond the expiration date, a new protocol must be submitted, reviewed, and approved [prior to expiration of the original or preceding protocol] as described in Paragraph III.D.6. above.

- 10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows: The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, the institution's Assurance, or IV.C.1.a.-g. of the PHS Policy. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present. If the IACUC suspends an activity involving animals, or any other institutional intervention results in the temporary or permanent suspension of an activity due to noncompliance with the Policy, Animal Welfare Act, the *Guide*, or the institution's Assurance, the Institutional Official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW.
- E. The occupational health and safety program for personnel working in laboratory animal facilities or that have frequent contact with animals is as E. The occupational health and safety program for personnel working in laboratory animal facilities or that have frequent contact with animals is as follows:
- 1. <u>Administration/Management</u>. The Director of Student Health Services has overall management (development, implementation, monitoring, etc.) responsibility for the program.

- 2. <u>Scope</u>. The program covers all personnel involved in laboratory animal care and/or use at ASU. Participation in the program is mandatory. The level of participation required is dependent upon the level of assessed risk.
- 3. <u>Hazard Identification and Risk Assessment</u>. The program is based on hazard identification, risk assessment, and developing and implementing measures to minimize identified hazards and risks. Procedures for Hazard and Risk Assessment involve Investigators input into their protocols, evaluation of the protocol by the IACUC, questionnaire review for specific and general risk factors, veterinarian input, as well as, physician consultation as needed. In addition, the IACUC looks to identify hazards, both actual and potential, during the semiannual program reviews and facility inspections.
- 4. <u>Health Histories and Evaluations</u>. All personnel are required to complete a health history questionnaire. Each questionaire along with the an applicable individual hazard identification and risk assessment form are evaluated by Director of Student Health. This process is completed initially and update/repeated at least annual. The health history forms are maintained at Student Health Center by the Director of Student Health. He/She will notify supervisors of any pertinent issues on a need to know basis.
- 5. <u>Common hazards and risks that have been identified.</u> Common hazards and risks, and procedures in place to minimize them are as follows:
 - a. Allergic reactions are among the most common conditions that adversely affect the health of personnel working with laboratory animals. Major sources of allergens include rodent urine and saliva. Measures taken to minimize exposure include the following: education, protective clothing, gloves, and hand washing. To reduce aerosol exposure, the use of bedding dump stations, appropriate hoods or laminar flow benches/cabinets, and/or other respiratory protection, e.g.,N95 masks, or appropriate respirator, are used.
 - b. Bites/Scratches Bites and scratches can expose individuals to biologic hazards which may be transmitted through saliva, secretions, and/or blood, though the risk is mitigated by the University's practice to purchase laboratory rodents from laboratories which exclude zoonotic agents. Exceptions would include: 1) animals that have been inoculated with biohazardous materials (e.g., LCMV); or 2) secondary bacterial infections that may occur when common skin and intestinal bacteria are present on the individual or the animal. Training in animal handling techniques and the use of appropriate personal protective equipment help to mitigate risks. Bites or scratches are washed immediately with soap (preferably an antiseptic soap, such as chlorhexidene-Nolvasan® or Betadine®-povidone iodine) and running water. If a bite/scratch wound is severe, or in the event of injury or illness due to animal exposure, individuals are instructed to seek immediate medical treatment at the Student Health Center on campus, a local extended hours clinic, or the St. Bernards hospital emergency room in the event the other two centers are closed.
 - c. Zoonoses Humans usually are susceptible to many infectious diseases suffered by animals and the potential exists through environmental exposure and by handling animals, body fluids, cultured microbial pathogens, tissues and tumors. Infection in animals may sometimes produce severe disease in humans even when the animals appear healthy. The majority or animals currently used at ASU are mice and rats that are purposely bred for research and are from specific pathogen free (SPF) colonies.

That is they are "clean." Nevertheless, standard universal precautions are used when handling the animals, their waste (dirty bedding), tissues, and bodily fluids.

- d. Biological Hazards Biological agent use is overseen by the Institutional Biosafety Committee (IBC) in collaboration with the Environmental Health and Safety Department. The IBC is responsible for the review of this institution's teaching projects and research activities involving the acquisition, use, storage, and disposal of Biohazardous agents. The EH&S Director and his staff work closely with the Program Veterinarian to provide training in the safe handling and management of biological and chemical agents used in studies with research animals. Detailed Biosafety requirements and safety procedures are contained in the Policies and Procedures for Biosafety
- e. Radioactive Hazards Radioactive material use must be authorized under the radioactive materials license issued to ASU by the Arkansas Department of Health. All projects must comply with pertinent regulations and relevant terms of this license. The Director of Environment Health and Safety (EH&S) oversees the ASU Radiation Safety Program. He/She monitors compliance with regulations, license conditions, and policies. Detailed policies and procedures governing the acquisition, use and disposal of radiation sources are found in the ASU Radiation Safety Manual.
- f. Chemical Hazards Chemical use is administered by the Department of EH&S through the Chemical Inventory/Hygiene Plan which is directed at controlling exposures to hazardous chemicals in laboratories. The Plan sets forth procedures, equipment, personal protective equipment, and practices that are capable of protecting employees from health hazards presented by hazardous chemicals used in laboratories and are capable of keeping chemical exposures below regulatory limits. Supervisors of researchers and husbandry/cage washing staff are responsible, with assistance from EH&S, for evaluating the potential exposure risks to their staff. Guidelines and operation specific exposure controls for occupational exposures to hazardous chemicals have been developed and are available to all employees.
- g. Physical Hazards Physical hazard identification and procedures for mitigation generally fall under the responsibilities of the EH&S Office. Examples include hazards that increase the risk of slips, trips, and falls, etc. Engineering practices and training are used to mitigate the hazard and risk respectively.
- 6. <u>Personnel Hygiene</u>. Appropriate clothing, depending on the area in which personnel are working and upon the species being used, is required. Facilities for maintaining personal hygiene are provided. Eating, drinking, and applying cosmetics is prohibited in all animal housing and procedure areas.
- 7. <u>Personal Protective Equipment (PPE)</u>. Personnel working with laboratory animals are required to wear appropriate clothing. As applicable, dedicated work clothing is provided and may be worn only within the Animal Care Facility or procedure areas. Appropriate personnel protective equipment (PPE) is provided in the gowning room at the entrance to the Animal Facility
- 8. <u>Immunization Requirements</u>. Personnel working directly with animals are required to provide evidence of recent (within the last 5 years) tetanus immunization. Other immunizations will be required on a case-by-case basis based on physican's input.

- 9. <u>Precautions taken regarding pregnancy</u>, illness or decreased immunocompetence. Personnel are advised during training that if they are planning to become pregnant, are pregnant, are ill, or have impaired immunocompetence that they should consult a health care professional/physician regarding such conditions and how they might pertain to their working with laboratory animals. If warranted, any work restrictions and/or accommodations are coordinated among the individual, his/or health care professional, human resources, etc.
- 10. Provisions for personnel who are not involved in animal care and/or use but nevertheless need to enter areas when animals are housed or used. For example personnel involved in building maintenance, security, housekeeping, etc. The housekeeping staff is not routinely allowed access to the animal facilities. In situations where housekeeping, maintenance, or other non-animal care and use personnel must access the animal rooms, they are briefed on appropriate precautions and provided any appropriate PPE and are then are permitted in for a limited amount of time. A member of the animal care staff will be available for escort if needed. If there is extensive or prolonged work to be done the animals are removed prior to the individuals being allowed into the room.
- 11. Availability and procedures for treatment in the event of illness or injury. Basic first-aid equipment is provided on-site. All Staff and students have access to the health center in the event of an animal related injury, or bite. If required, treatment is also available at the local extended hours clinic, or the St. Bernards Hospital.
- 12. <u>Procedures/program for reporting and tracking injuries and illnesses</u>. Occupational injuries are monitored by the Environmental Health and Safety Office (through the Human Resources Department). Report of all work-related illness and/or injury is mandatory. This requirement is covered and during OH&S training and Animal Care & Use Training.
- 13. OH&S Training. Training (e.g., on zoonoses, allergies, hazards, special precautions for pregnancy, illness, and immune suppression) is provided through targeted, CITI Program in-service training, programs and seminars. These programs, in addition to educational materials sent via email to all animal users, emphasize the specific risks associated with different types of research with laboratory animals and provide guidance on appropriate methods of exposure control and protection. New personnel who use or handle animals are required to complete initial training, be enrolled in the OH&S Program, including completing health questionnaire, and are provided with Health Hazard Protocols and Pathogen identification information before starting work.
- 14. <u>Miscellaneous</u>. Safe laboratory practices and common sense lessens the risk of infection and accidents. The CDC/NIH manual, Biosafety in Microbiological and Biomedical Laboratories, provides guidance on biosafety procedures for a wide spectrum of microbial agents with potential for human infection. Control of Communicable Disease in Man, published by the American Public Health Association, is another excellent resource for information concerning zoonotic diseases and infection control. Copies of both of these references are maintained by the Director of Student Health.
- F. 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 Facility and Species Inventory table (Attachment B).

G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

IACUC Training - Each IACUC member will be provided with a copy of the following:

- 1) The PHS Policy for the Humane Care and Use of Laboratory Animals;
- 2) The National Research Council (NRC) Guide for the Care and Use of Laboratory Animals;
- 3) The ARENA/OLAW IACUC Guidebook;
- 4) The AVMA Guidelines on Euthanasia;
- 5) A copy of this Assurance.

All members of the IACUC will complete the Essentials for IACUC Members Curriculum located at the American Association for Laboratory Animal Science website, www.aalaslearninglibrary.org or the Collaborative Institutional Training Initiative website, www.citiprogram.org

All IACUC members will visit the OLAW website at least semi-annually and will complete the IACUC tutorial module (initial visit) and will familiarize themselves with the other pertinent modules and information, e.g., OLAW FAQs, Policies and Laws, Guidance, Educational and other Resources.

Attendance at an IACUC 101, IACUC 102, IACUC Advanced, PRIM&R/ARENA IACUC meeting, or similar course may be substituted for any required IACUC training session.

Animal Care and Use Personnel – The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows: All personnel performing procedures using animals must be identified in the Institutional Animal Care and Use Protocol. A description of each individual's qualifications, experience and/or training with the specific animal species, model and procedures must be provided for IACUC review. Any person needing additional protocol-specific training will be identified during the review process and such required training will be a condition of approval of the protocol.

All persons involved in animal care and use will be required to attend an orientation seminar given by the IACUC Chair, Consulting Veterinarian, or other qualified individual(s), which covers the laws and regulations covering laboratory animal care and use with an emphasis on the contents of the NRC Guide and the 3R's. The training includes training or instruction on research or testing methods that minimize the numbers of animals required to obtain valid results and limit animal pain or distress as well as other requirements delineated in 9 CFR, Part 2, Subpart C, Section 2.32(c).

Specifically, training and instruction of personnel must include guidance in at least the following areas:

- 1. Humane methods of animal maintenance and experimentation, including:
 - a. The basic needs of each species of animal;
 - b. Proper handling and care for the various species of animals used by the facility;
 - c. Proper pre-procedural and post-procedural care of animals; and
 - d. Aseptic surgical methods and procedures;
- 2. The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress:

- 3. Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility;
- 4. Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act;
- 5. Utilization of services (e.g., National Agricultural Library, National Library of Medicine) available to provide information:
 - a. On appropriate methods of animal care and use;
 - b. On alternatives to the use of live animals in research;
 - c. That could prevent unintended and unnecessary duplication of research involving animals; and
 - d. Regarding the intent and requirements of the Animal Welfare Act and USDA-APHIS Regulations

On-line training may be used and accepted in lieu in-house training. Any use of on-line training to fulfill training requirements must be approved by the IACUC. Approval and completion of on-line training will be documented.

Specialized Training: Training in experimental methods, i.e., specific animal manipulations and techniques and in the care of new and nontraditional laboratory animal species, will be conducted based on the types of research being conducted and the species being used at the institution.

Note: For investigators transferring from other facilities at which they have received similar training, verification of previous training <u>may</u> be accepted in lieu <u>some</u> Institutional required training. Acceptance of previous training in lieu of the Institution's training is solely at the IACUC's discretion.

All investigators involved in the care and use of animals shall have access to a copy of the "Animal Care Facility Training Manual." Principal Investigators will be required to keep a copy of the manual in their laboratories for the use of all personnel. Investigators are expected to review the manual prior to completing an Animal Protocol Form and to ensure that all staff and students under their supervision are also familiar with the policies outlined in the manual.

Mandatory training seminars are generally presented at least once per semester. All attendees will sign a statement of attendance which will be kept on file in the Animal Care Facility office.

IV. INSTITUTIONAL PROGRAM EVALUATION AND ACCREDITATION

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past six months and will be re-evaluated by the IACUC at least once every six months thereafter, in accord with the PHS Policy IV.B.1-2. Reports have been and will continue to be prepared in accord with the PHS Policy IV.B.3. All IACUC 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 IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

This Institution is Category Two (2)—not accredited by the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request. The report of the most recent evaluations (program review and facility inspection) is attached (Attachment C).

V. RECORDKEEPING REQUIREMENTS

- 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 IACUC 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 IACUC approval was given or withheld.
 - Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, the Associate Chancellor for Research.
 - 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 IACUC 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 <u>January 1 December 31</u>. After the end of the reporting period, the IACUC, through the Institutional Official, will submit an annual report to OLAW no later than **January 31**. The report will include:
 - Any change in the accreditation status of the Institution (e.g., if the Institution
 obtains accreditation 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 change in the IACUC membership. If there are no changes
 to report, this Institution will provide written notification that there are no changes.

- 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 the Institutional Official, the Associate Chancellor for Research.
- B. The IACUC, 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 provisions of the "Guide."
 - 3. Any suspension of an activity by the IACUC.
- C. Reports filed under sections VI.A. and VI.B. of this document shall include any minority views filed by members of the IACUC.

VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A. Authorized Institutional Official	
Name: Dr. Michael Dockter	
Title: Vice Chancellor of Research and Academic Affairs	
Name of Institution: Arkansas State University	
Address: Arkansas Biosciences Institute, Research and Academic Aft P.O. Box 2760, State University, AR 72467	fairs
Phone: 870-972-2694	
Fax: 870-972-2336	
E-mail: mdockter@astate.edu	
Signature: 5/2/6	
Date: 5/21/10	
B. PHS Approving Official	
Name:	
Title:	
Address:	
Phone:	
Fax:	
E-mail:	
Signature:	
Date:	
C. Effective Date of Assurance:	
D. Expiration Date of Assurance:	

Attachment A

MEMBERSHIP OF THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

DATE: April 2010 NAME OF INSTITUTION: Arkansas State University ASSURANCE NUMBER: A4506-01

Chairperson Name, Title, and Degree/Credentials	Business Address, Pho	Business Address, Phone, Fax, and Email of Chairperson	оп
Name*: Dr. Kristin Biondolillo	Address*: 504 University L State University, AR 72467	Address*: 504 University Loop East, Room 101 State University, AR 72467	
Title*: Associate Professor of Biology			
Degree/credentials*: Ph.D. Experimental Psychology	Phone*: 870-972-3064	Fax*: 870-972-3962	Email*: kdbiondo@astate.edu
Name of Member/Code**	Degree/Credentials	Position Title	PHS Policy Requirements***
Bednarz, James	Ph.D. Biology	Professor, Wildlife Ecology	
Biondolillo, Kristin	Ph.D. Experimental Psychology	Assoc. Professor, Psychology	Scientist
Cooper, Brandon	Pharm.D.	Pharmacist, Soo's Drug	Unaffiliated Member
Curry, Steven	MA, Counseling Therapy	Counselor	Non-affiliated Member
Drake, Shawn	Ph.D. Human Performance	Asst. Prof., Physical Therapy	Scientist
Grippo, Anne	Ph.D. Biology	Associate Professor, Biology	Scientist
McMickle, Anthony	B.S. Biology, RALAT	Animal Facility Manager	Member
Moeeni, Farhad	Ph.D., Computer and	Professor, Computer and	Non-scientist
	Information Technology	Information Technology	
Ryan, Archie	D.V.M.	Veterinarian	Veterinarian
Srivatsan, Malathi	Ph.D., Molecular	Assistant Professor, Biology	Scientist
	Neuroscience		

*This information is mandatory.

and the identity of each member must be readily ascertainable by the Institution and available to authorized OLAW or other submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided **Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this PHS representatives upon request.

***PHS Policy Requirements - identify which IACUC members meet the four criteria below:

- Veterinarian (V) a veterinarian with direct or delegated program responsibility.
- Scientist (S) a practicing scientist experienced in research involving animals.
- Nonscientist (NS) a member whose primary concerns are in non-scientific areas (e.g. ethicist, lawyer, member of the
- represent the interests of the general community in the proper care and use of animals and should not be a laboratory IACUC, and who is not a member of the immediate family of a person who is affiliated. This member is expected to Nonaffiliated (NA) - a member who is not affiliated with the Institution in any way other than as a member of the animal user. A consulting attending veterinarian may not be considered nonaffiliated.

Notes:

- must be voting members. Ad hoc or nonvoting members may be listed and identified as such, but are not considered 1. All members must be appointed by the CEO (or individual with specific written delegation to appoint members) and members for the purpose of the PHS Policy, and do not contribute to a quorum.
- If Alternate members are listed, identify for whom (by name or code number, not specialty) they will serve as 2

OTHER KEY CONTACTS (OPTIONAL)

If there are other individuals within the Institution who may be contacted regarding this Assurance, please provide information below.

Name: Marie H. Dockter

Fitle: Director of Research Administration and Compliance

Phone & Fax: (870) 972-2168 & (870) 972-2336

E-mail: mhdockter@astate.edu

Name: Anthony McMickle

Fitle: Director, Animal Care and Use

Phone & Fax: (870) 972-2025 & (870) 972-2026

E-mail: amcmickle@astate.edu

Attachment B

FACILITY AND SPECIES INVENTORY

DATE: April 2010 NAME OF INSTITUTION: Arkansas State University ASSURANCE NUMBER: A4506-01

		T							_		
Approx. Average Daily Inventory	196	12									
Species Housed in Unit (use complete common names)	Mice ¹ Rats ¹	Rats ¹									
Gross Square Feet (including service areas)	4620 square reet	186 square feet									
ding*	ABI Anımal Care Facility	Psychology Holding Facility									
Labe	ABI	Psyc									

¹Mice of the genus mus and rats of the genus rattus that are purpose bred for research.

ATTACHMENT C PROGRAM AND FACILITY REVIEW

Dr. Venita Thornton, Sr. Assurance Officer

Office of Laboratory Animal Welfare

6705 Rockledge Dr., Bethesda, MD

National Institutes of Health

RKL 1, Suite 360, MSC 7982



P.O. Box 1560 State University, AR 72467-1560

Phone

870-972-3064

Fax:

870-972-3962

www.astate.edu

Jonesboro, Arkansas

Dear Dr. Thornton:

20892-7982

Please see the attached revised Annual Report to OLAW from Arkansas State University. Our conversation on April 1, 2010 brought to my attention that we had failed to report a semi-annual program review and facility inspection. The Arkansas State University IACUC conducted a review/inspection on January 21, 2009 that was not included on the 2008 or 2009 annual reports. I have revised the 2009 report to include this review.

Sincerely,

Kris Biondolillo, Chair

Arkansas State University IACUC

ANNUAL REPORT TO OLAW

Revised April 1, 2010

INSTITU	JTION: Arkansas State University
REPORT	TING PERIOD: 01/01/09-12/31/09 ASSURANCE NUMBER: A4506-01
Institutio	itution's Institutional Animal Care and Use Committee (IACUC), through the nal Official, hereby provides this Annual Report to the Office of Laboratory Animal (OLAW).
1. PROC	GRAM CHANGES (Select A. or B. only)
[]	A. There have been no changes in this Institution's program for animal care and use as described in the Assurance (Go to Item 2.)
[x]	B. Change(s) in this Institution's program for animal care and use as described in the Assurance have occurred during this reporting period (select all that apply):
	[] This Institution's AAALAC accreditation status has changed (PHS Policy IV.A.2.).
	The entire animal care and use program is now: [] AAALAC Accredited (Category 1) [] Non-Accredited (Category 2) [] This Institution's program for animal care and use has changed (PHS Policy IV.A.1. a-i). (Please attach a full description of such changes). [] The individual designated by this Institution as the Institutional Official has changed. (Please attach name, title(s), address, telephone and fax number). [x] The Chairperson of this Institution's IACUC has changed. (Please attach name, title(s), address, telephone and fax number). [x] The membership of this Institution's IACUC has changed. (Please attach a new roster of members).

2. SEMIANNUAL EVALUATIONS

This IACUC has conducted semiannual evaluations of the Institution's program and inspections of the Institution's facilities (including satellite facilities) on the following dates. Reports of the evaluations and inspections have been submitted to the Institutional Official. If significant and/or minor deficiencies were identified, a plan and schedule for correction of each was included in the reports.

A. Program Evaluations: Two dates (month/day/yr) must be provided to satisfy the Policy requirement that evaluations be done at six month intervals. If the IACUC conducted more than

two evaluations of the program during the reporting period, please attach a list showing the dates.

Date 3: January 7, 2010 Date 1: January 21, 2009 Date 2: September 03, 2009

B. Facility Inspections: Two dates (month/day/yr) must be provided to satisfy the Policy requirement that facility inspections be done at six month intervals. If the IACUC conducted more than two inspections of each site during the reporting period, please attach a list showing the dates.

Date 3: January 7, 2010 Date 1: January 21, 2009 Date 2: September 03, 2009

3. MINORITY VIEWS

Any minority views submitted by members of the IACUC regarding reports filed under Section IV.F. of the PHS Policy for this reporting cycle are attached. NA

ning a so

Institutional Official Chairperson, IACUC Name: Michael Dockter Name: Kris Biondolillo

Date: April 1, 2010 Date:

Membership of the Institutional Animal Care and Use Committee

Name of Institution: Arkansas State University

Assurance Number: A4506-01 Date: August 15, 2009

Chairperson Name, Title, and Business Address, Phone, Fax, and Email of Chairperson Degree/Credentials

Address: Department of Psychology and Counseling, P.O. Box 1560, State Name: Kris Biondolillo

University, AR 72467

Title: Associate Professor of Psychology

Degree/Credential: Ph.D. Email: Phone: 870-680-4330 Fax: 870-972- 3962

Experimental Psychology kdbiondo@astate.edu

Name of Member/Code*	Degree/Credentials	Position Title	PHS Policy Membership Requirements**
Jim Bednarz	Ph.D. Biology	Professor, Wildlife Ecology	Scientist
Shawn Drake	Ph.D. Human Performance	Associate Professor, Physical Therapy	Non-Scientist
Steven Curry	M.A. Counseling Psychotherapy	High School LPC	Nonaffiliated Member
Brandon Cooper	Pharm.D.	Pharmacist, Soo's Drug Store	Nonaffiliated Member (alternate)
Marie Dockter	M.P.A.	Research Compliance Officer	Administrative Member
Anne Grippo	Ph.D. Medicinal Chemistry	Associate Professor, Biological Sciences	Scientist
Tony McMickle	B.S. Biology, RALAT	Animal Care Facility Manager	Scientist
Farhad Moeeni	Ph.D.	Professor, Computer and Information Technology	Non-scientist
Archie Ryan	D.V.M.	Veterinarian	Veterinarian
Malathi Srivatsan	Ph.D. Molecular Neuroscience	Assistant Professor, Biology	Scientist
Kris Biondolillo	Ph.D. Experimental Psychology	Associate Professor, Psychology	Scientist

. .

* Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

NOTE: Non-voting members must be so identified.

** - PHS Policy Membership Requirements:

Veterinarian - a veterinarian with direct or delegated program responsibility

Scientist - a practicing scientist experienced in research involving animals

Nonscientist - a member whose primary concerns are in a nonscientific area (e.g. ethicist, lawyer, member of the clergy)

Nonaffiliated- a member who is not affiliated with the institution in any way other than as a member of the IACUC, member and who is not a member of the immediate family of a person who is affiliated. This member is expected to represent general community interests in the proper care and use of animals and should not

be a laboratory animal user. A consulting attending veterinarian may not be considered nonaffiliated.

ANNUAL REPORT TO OLAW

INSTITUTION: Arkansas State University

REPORTING PERIOD: 01/01/09-12/31/09 ASSURANCE NUMBER: A4506-01

This Institution's Institutional Animal Care and Use Committee (IACUC), through the Institutional Official, hereby provides this Annual Report to the Office of Laboratory Animal Welfare (OLAW).

1. PROGRAM	CHANGES	(Select A.	or B. onl	y)

[]	A. There have been no changes in this Institution's program for animal care and use as described in the Assurance (Go to Item 2.)
[x]	B. Change(s) in this Institution's program for animal care and use as described in the Assurance have occurred during this reporting period (select all that apply):
	[] This Institution's AAALAC accreditation status has changed (PHS Policy IV.A.2.).
	The entire animal care and use program is now: [] AAALAC Accredited (Category 1) [] Non-Accredited (Category 2) [] This Institution's program for animal care and use has changed (PHS Policy IV.A.1. a-i). (Please attach a full description of such changes). [] The individual designated by this Institution as the Institutional Official has changed. (Please attach name, title(s), address, telephone and fax number). [x] The Chairperson of this Institution's IACUC has changed. (Please attach name, title(s), address, telephone and fax number).

2. SEMIANNUAL EVALUATIONS

This IACUC has conducted semiannual evaluations of the Institution's program and inspections of the Institution's facilities (including satellite facilities) on the following dates. Reports of the evaluations and inspections have been submitted to the Institutional Official. If significant and/or minor deficiencies were identified, a plan and schedule for correction of each was included in the reports.

[x] The membership of this Institution's IACUC has changed.

(Please attach a new roster of members).

A. Program Evaluations: Two dates (month/day/yr) must be provided to satisfy the Policy requirement that evaluations be done at six month intervals. If the IACUC conducted more than two evaluations of the program during the reporting period, please attach a list showing the dates.

Date 1: September 03, 2009 Date 2: January 7, 2010 **B. Facility Inspections:** Two dates (month/day/yr) must be provided to satisfy the Policy requirement that facility inspections be done at six month intervals. If the IACUC conducted more than two inspections of each site during the reporting period, please attach a list showing the dates. Date 1: September 03, 2009 Date 2: January 7, 2010 3. MINORITY VIEWS Any minority views submitted by members of the IACUC regarding reports filed under Section IV.F. of the PHS Policy for this reporting cycle are attached. NA milk Institutional Official Chairperson, IACUC Name: Michael Dockter Name: Kris Biondolillo Date: January 7, 2010 Date: Vanuary 18,2010 Membership of the Institutional Animal Care and Use Committee Name of Institution: Arkansas State University Assurance Number: A4506-01 Date: August 15, 2009 Chairperson Name, Title, and Business Address, Phone, Fax, and Email of Chairperson Degree/Credentials Name: Kris Biondolillo Address: Department of Psychology and Counseling, P.O. Box 1560, State University, AR 72467 Title: Associate Professor of Psychology Degree/Credential: Ph.D. Email: Phone: 870-680-4330 Fax: 870-972- 3962 kdbiondo@astate.edu Experimental Psychology **PHS Policy** Name of Degree/Credentials **Position Title** Membership Member/Code* Requirements**

Jim Bednarz

Ph.D. Biology

Professor, Wildlife

Ecology

Scientist

Shawn Drake	Ph.D. Human Performance	Associate Professor, Physical Therapy	Non-Scientist
Steven Curry	M.A. Counseling Psychotherapy	High School LPC	Nonaffiliated Member
Brandon Cooper	Pharm.D.	Pharmacist, Soo's Drug Store	Nonaffiliated Member (alternate)
Marie Dockter	M.P.A.	Research Compliance Officer	Administrative Member
Anne Grippo	Ph.D. Medicinal Chemistry	Associate Professor, Biological Sciences	Scientist
Tony McMickle	B.S. Biology, RALAT	Animal Care Facility Manager	Scientist
Farhad Moeeni	Ph.D.	Professor, Computer and Information Technology	Non-scientist
Archie Ryan	D.V.M.	Veterinarian	Veterinarian
Malathi Srivatsan	Ph.D. Molecular Neuroscience	Assistant Professor, Biology	Scientist
Kris Biondolillo	Ph.D. Experimental Psychology	Associate Professor, Psychology	Scientist

NOTE: Non-voting members must be so identified.

^{*} Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

** - PHS Policy Membership Requirements:

Veterinarian - a veterinarian with direct or delegated program responsibility

Scientist - a practicing scientist experienced in research involving animals

Nonscientist - a member whose primary concerns are in a nonscientific area (e.g. ethicist, lawyer, member of the clergy)

Nonaffiliated- a member who is not affiliated with the institution in any way other than as a member of the IACUC, member and who is not a member of the immediate family of a person who is affiliated. This member is

expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting attending veterinarian may not be considered nonaffiliated.

Arkansas State University

Institutional Animal Care and Use Committee
Semiannual Program and Facility Review

January 7, 2010

INSTITUTIONAL POLICIES AND RESPONSIBILITIES

DATE: January 07, 2010 *A M S

DATE. January 07, 2010	_ *A	M	S
1. IACUC MEMBERSHIP AND FUNCTIONS			
- at least 5 members, appointed by CEO	*		
- members include veterinarian, scientist, non-scientist, and non-affiliated non-lab animal user ¹	*		
- responsible for oversight and evaluation of institution's program	*		
- reports to Institutional Official (IO)	*		
- conducts semiannual evaluations of institutional animal care and use program	*		
- conducts semiannual inspections of institutional animal facilities	*		
- reviews and investigates concerns about animal care and use at institution ²	*		
- procedures for review, approval and suspension of animal activities ³	*		
- procedures for review & approval of significant changes to approved activities	*		
- policies for special procedures (e.g. restraint, multiple survival surgery, fluid restriction) ⁴	*		
2. IACUC RECORDS AND REPORTING REQUIREMENTS ⁵			
Reports to Institutional Official (IO)			_
- reports of semiannual program reviews & facility inspections are submitted to 10^6	*		
- include minority IACUC views	*		
- describe departures from <i>Guide</i> or PHS Policy and reasons for departure ⁷	*		
- distinguish significant from minor deficiencies	*		
- include plan and schedule for correction of each deficiency identified ⁸	*		
Reports to Office of Laboratory Animal Welfare (OLAW)			
- reports include any minority IACUC views	*		
- annual report to OLAW documents program changes & dates of IACUC semiannual review	*		
- promptly advises OLAW of serious/ongoing Guide deviations or PHS Policy noncompliance	*		
- promptly advises OLAW of any suspension of activity by the IACUC	*		
Reports to United States Department of Agriculture (USDA)			
- annual report contains required information	*		
- reporting mechanism in place for IACUC-approved exceptions to the regulations and standards	*		
- reports within 15 days failure to adhere to timetable for correction of deficiencies	*		
- reports suspension of activity by the IACUC to USDA and any Federal funding agency	*		
Records			
- minutes of IACUC meetings and semiannual reports maintained for 3 years	*		
- IACUC review documentation maintained for 3 years after end of study	*		
- IACUC review of activities involving animals includes all required information9	*		
3. VETERINARY CARE (See also next section - Veterinary Medical Care)			
- institutional arrangement for veterinarian with training or experience in lab animal medicine 10	*	_	
- veterinary access to all animals	*		
- provision for backup veterinary care	*		
- must provide guidance on handling, immobilization, sedation, analgesia, anesthesia, euthanasia	*		
- must provide guidance/oversight on surgery programs and oversight of postsurgical care	*		
- veterinary authority to oversee all aspects of animal care and use	*		

^{*}A = acceptable; M = minor deficiency; S = significant deficiency (is or may be a threat to animal health or safety)

INSTITUTIONAL POLICIES AND RESPONSIBILITIES (cont.)

		IVI	3
4. PERSONNEL QUALIFICATIONS AND TRAINING			
- institution has established and implemented an effective training program	*		
- includes professional/management/supervisory personnel	*		
- includes animal care personnel	*		
- includes research investigators, instructors, technicians, trainees, students	*		
Training program content			
- humane practices of animal care (e.g. housing, husbandry, handling) ¹¹	*		
- humane practices of animal use (e.g. research procedures, use of anesthesia, pre- & post-operative care) 12	*		
- research/testing methods that minimize numbers necessary to obtain valid results	*		
- research/testing methods that minimize animal pain or distress	*		
- use of hazardous agents, including access to OSHA chemical hazard notices where applicable	*		
5. OCCUPATIONAL HEALTH AND SAFETY OF PERSONNEL			_
Institutional program for a safe and healthy workplace			
- program is established and implemented	*		
- covers <i>all</i> personnel who work in laboratory animal facilities	*		
- based on hazard identification and risk assessment	*		_
- personnel training (e.g. zoonoses, hazards, pregnancy/illness/immunosuppression precautions)	*	-	_
- personal hygiene procedures (e.g., work clothing, eating/drinking/smoking policies)	*		_
- procedures for use, storage & disposal of hazardous biologic, chemical, and physical agents	*		-
- specific procedures for personnel protection (e.g., shower/change facilities, injury prevention)	*		-
Program for medical evaluation and preventive medicine for personnel			
- pre-employment evaluation including health history	*		
- immunizations as appropriate (e.g. rabies, tetanus) & tests	*		
- zoonosis surveillance as appropriate (e.g. Q-fever, tularemia, Hantavirus, plague)	*		
- procedures for reporting and treating injuries, including bites etc.	*		
Special precautions for personnel who work with primates			
- tuberculosis screening includes all exposed personnel			
- training and implementation of procedures for bites & scratches			
- education regarding Cercopithecine herpesvirus 1 (Herpes B)		-	-
Notes: Focused effort has gone into improving, even further, the training of individuals who serve on the IACUC, or research with nonhumans, and utilize or have access to the research facilities. Improved documentation of training received and expanded training opportunities are one result of these efforts.		uct	

^{*}A = acceptable; M = minor deficiency; S = significant deficiency (is or may be a threat to animal health or safety)

VETERINARY MEDICAL CARE

DATE: January 07, 2010 *A M S

	_^A		
1. PREVENTIVE MEDICINE/ANIMAL PROCUREMENT & TRANSPORTATION	-		
- evaluation of animal vendors	*		
- procedures for lawful animal procurement, evaluation of animals, & transport	*		
- procedures for quarantine, stabilization	*		
- policies on separation by species, source, health status	*		
- policies for isolation of sick animals	*		
- program of surveillance, diagnosis, treatment and control of disease	*		
- availability of diagnostic resources for preventive health program	*		
- provision for emergency, weekend and holiday veterinary care	*	\neg	
2. SURGERY	\		
- procedures for monitoring surgical anesthesia and analgesia	*		
- pre-surgical plan (e.g. identify space, supplies, conduct pre-op exam, define post-op care)	*	\neg	
- appropriate training or experience of personnel in surgery & anesthesia	*		
- major procedures distinguished from minor	*		
- use of effective aseptic procedures for survival surgery	*		
- implemented procedures for use of surgical facility	*		
- implemented procedures for using/scavenging volatile anesthetics	*		
- effective procedures for sterilizing instruments & monitoring expiration dates on sterile packs	*		_
- documentation of post-operative monitoring and care	*		
3. PAIN, DISTRESS, ANALGESIA, AND ANESTHESIA			
- guidelines for assessment and categorization of pain	*		
- IACUC guidelines for avoiding unnecessary pain and distress	*		
- appropriate anesthetics, analgesics, tranquilizers used for each species	*		
- special precautions for the use of paralytics ¹³	*		
- veterinary input in the choice of drugs	*		_
4. EUTHANASIA	ــــــــــــــــــــــــــــــــــــــ		
- compliance with current AVMA Panel on Euthanasia unless approved by the IACUC	*		_
- guidance provided on appropriate methods for each species	*	\neg	_
- training available for personnel in humane methods of euthanasia	*		_
5. DRUG STORAGE AND CONTROL	Щ.		
- safe, secure, storage arrangement	*		_
- record keeping meets regulations	*	\neg	_
- procedures exist for ensuring drugs are within expiration date	*		i —
- procedures exist for ensuring drugs are within expiration date	1 1		$\overline{}$

^{*}A = acceptable; M = minor deficiency; S = significant deficiency (is or may be a threat to animal health or safety)

ANIMAL HOUSING & SUPPORT AREAS

DATE: January 07, 2010

DATE. January	
Location:	animal areas separate from personnel areas, separation of species, separation by disease statu
	corridors, doors, windows, floors, drainage, walls, ceilings, HVAC, power & lighting, noise
Room/cage:	temperature, humidity, ventilation, illumination, noise control
Cage/run :	sanitation, cleaning tools, food/water access, security, safety, allows undisturbed observation size, 14 rationale for <i>Guide</i> / USDA exceptions, meets physiologic, behavioral, 15 social 16 needs
Sheltered or o	utdoor housing (barns, corrals, pastures, islands):
	weather protection, ventilation & sanitation of shelters (no waste/moisture build-up),
	animal acclimation, social compatibility, roundup/restraint procedures, security
Behavioral ma	inagement: environmental enrichment, social grouping, animal activity
Food:	feeding schedule & procedures, contamination, vendor quality control,
	storage in sealed containers, expiration date labeling, vermin control, rotation of stocks
Water:	ad libitum unless justified, QC procedures
Bedding:	species appropriate, keeps animals dry, QC procedures, minimizes scientific variables
Sanitation:	frequency of bedding change (note Guide exceptions), cleaning & disinfection, monitoring
Waste disposa	al: procedures for collection, storage & disposal of waste; hazardous waste; animal carcasse
Pest control:	regularly scheduled, documented program including control of rodent pests & insecticide us
Emergency, w	reekend, & holiday animal care: provision for, accessible contact information, monitoring
	of backup systems, veterinary care
Animal identif	ication and records: cage/rack cards contain required information, clinical records accessible and appropriate
Genetics and	nomenclature: appropriate genetic records & monitoring procedures, use of standardized
	nomenclature
Storage:	food and bedding, supplies, drugs & biologics, waste material, hazardous material, carcasses
Personnel:	locker rooms, administration and training
Specialized sp	·
LOCATION	*A M S NOTES
LOCATION	A III O NOTES

LOCATION	_*A	_M	S	NOTES NOTES
ABI		*		Enrichment treats need to be in closed container
		*		Personnel should wear hair net and mask while cleaning cages
		*		All personnel entering facility are required to wear facility lab coats
Psychology	*			
		-		

^{*}A = acceptable; M = minor deficiency; S = significant deficiency (is or may be a threat to animal health or safety)

CAGEWASH

DATE: January 07, 2010

Construction:

- doors, windows, floors, drainage, walls, ceilings (see Guide)
- convenient to animal areas/waste disposal
- ease of access (including door size) facilitates use
- sufficient space for workload
- safety precautions/clothing/equipment used for bedding disposal/prewash/acid wash
- traffic flow clean to dirty with no contamination of clean equipment by dirty equipment
- insulation and/or sound attenuation present as needed
- utilities are appropriate
- ventilation meets heat and humidity load and Guide requirements
- safety features (SOP's, warning signs, eyewash station) are in use
- cagewash temperatures are monitored & records are available
- appropriate clean cage storage

LOCATION	*A	М	s	NOTES
ABI	*			
Psychology				Small number of animals are housed in the psych facility (< 30); holding cages are transported to ABI facility for washing and exchange.
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^{*}A = acceptable; M = minor deficiency; S = significant deficiency (is or may be a threat to animal health or safety)

ASEPTIC SURGERY

DATE: January 07, 2010

General Considerations:

- location minimizes traffic/contamination
- functional components (surgical support, animal preparation, surgeon scrub, operating room, postoperative recovery) are designed and separated (physically or otherwise) according to the *Guide*
- appropriate drug storage, control, expiration date monitoring
- safe sharps disposal system
- adequate records of anesthesia and perioperative care
- aseptic procedures in use for all survival surgery

Operating Room:

- effective contamination control procedures
- effective cleaning procedures/dedicated tools
- interior surfaces smooth and impervious to moisture
- HVAC system meets Guide requirements
- lighting safe and appropriate
- outlets safe and appropriate
- scavenging of anesthetic gases implemented
- warning signs posted where needed
- fixed equipment is sanitizable

Surgical support:

- facility for washing, sterilizing, storing instruments & supplies
- autoclave monitoring procedures are implemented
- storage of autoclaved materials maintains sterility
- cold sterilization procedures are appropriate

Animal preparation: contains large sink to facilitate cleaning of animal and operative site

Surgeon scrub: outside operating room, non-hand-operated sink

Postoperative recovery: allows adequate observation, easily cleaned, supports physiologic functions,

minimizes risk of injury

Dressing area: place for personnel to change

LOCATION	_ ` A	IVI	5	NOTES
Psychology				No surgical or invasive procedures are performed in the psychology facility.
ABI	*			

^{*}A = acceptable; M = minor deficiency; S = significant deficiency (is or may be a threat to animal health or safety)

PROCEDURE AREAS, NON-SURVIVAL SURGERIES, LABORATORIES, RODENT SURGERIES

DATE: January 07, 2010

General concerns:

- drug storage, control, and expiration dates
- sharps disposal
- anesthetic monitoring
- gas cylinders immobilized
- scavenging of anesthetic gases
- warning signs
- carcass disposal

Additional concerns for survival surgery (rodent or minor procedures only):

- rodent survival surgery clean and uncluttered, not used for anything else during surgery
- records of perioperative care
- aseptic procedures
- autoclave monitoring procedures
- storage of autoclaved materials
- cold sterilization procedures are appropriate

*A	M	S	NOTES
			NA .
	*		More surgery information cards needed in surgery room
	-		
	*A		*A M S

^{*} A = acceptable; M = minor deficiency; S = significant deficiency (is or may be a threat to animal health or safety)

SAMPLE SEMIANNUAL FACILITY INSPECTION CHECKLIST

[Use this page when additional space is needed for facility inspection comments]

DATE: January 07, 2010

LOCATION	*A	М	s	NOTES
Psychology		*		Signage identifying IACUC members and chair needs updated
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^{*}A = acceptable; M = minor deficiency; S = significant deficiency (is or may be a threat to animal health or safety)

SEMIANNUAL PROGRAM & FACILITY REVIEW REPORT

DATE: January 07, 2010

MEMBERS	IN AT	TENDANCE:	MEMBERS IN ATTENDANCE: James Bednarz, Kris Biondolillo(chair), Anne Grippo, Anthony McMickle, Archie Ryan	IcMickle, Arc	hie Ryan	
Deficiency Category (S or M)	*	Location	Deficiency & Plan for Correction	Responsible Party	Correction Schedule & Interim Status	Date Complete
W		Psychology	Update signage to reflect current IACUC membership	Kris Biondolillo	Correct by 1/15/10	1/11/10
Σ		ABI	Ensure adequate number of information cards in surgery room	Tony McMickle	Correct by 1/15/10	1/11/10
×		ABI	Enrichment treats in closed container	Tony McMickle	Correct by 1/15/10	1/11/10
×		ABI	Facility personnel instructed to wear hair net and mask during cage cleaning	Tony McMickle	Correct by 1/15/10	1/13/10
M		ABI	All personnel entering facility are required to wear facility lab coats. Signage indicating this will be posted.	Tony McMickle	Correct by 1/15/10	1/13/10
	-					

S = significant deficiency, M = minor deficiency (a significant deficiency is or may be a threat to animal health or safety)

^{*}Check if repeat deficiency

Endnotes - Selected USDA Regulatory Requirements that Differ from the PHS Policy

- 2.31(d)(1)(iii) "The PI has provided written assurance that the activities do not unnecessarily duplicate previous experiments."
- 2.31(d)(1)(iv) "Procedures that may cause more than momentary or slight pain or distress to the animals will:
 involve in their planning, consultation with the attending veterinarian or his or her designee; [PHS Policy does not specify veterinary consultation]
 - not include paralytics without the use of anesthesia;"
- 2.31(d)(1)(x) "No animal will be used in more than one major operative procedure from which it is allowed to recover, unless justified for scientific reasons by the principal investigator, in writing..."

¹Part 2 Subpart C- Research Facilities

^{- 2.31(}b)(2) - "The Committee shall be composed of a Chairman and at least two additional members;... at least one shall not be affiliated in any way with the facility...such person will provide representation for general community interests in the proper care and treatment of animals." [PHS policy requires 5 members]

² 2.32(c)(4) - "...No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act." [USDA requirement additional to PHS Policy]

³ 2.31(d)(5) - "...shall conduct continuing reviews of activities...not less than annually." [PHS Policy requires a complete new review every 3 years utilizing all the criteria for initial review]

⁴ 2.31(d)(1)(x) - "...no animal will be used in more than one major operative procedure from which it is allowed to recover unless...(it is) justified for scientific reasons...(or is) required as routine veterinary procedure...or other special circumstances as determined by the Administrator on an individual basis." [this last point is an additional USDA justification for multiple survival surgeries]

⁵ 2.36 - "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]

⁶ 2.31(c)(3) - "...The reports shall be reviewed and signed by a majority of committee members..."[USDA requirement additional]

⁷ 2.36(b)(3) - "...exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such exceptions must be attached to the facility's annual report." [Refers to USDA annual report]

⁸ 2.31 (c)(3) - "...Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the institutional official, to APHIS and any Federal agency funding that activity." [PHS Policy requires prompt reporting to OPRR of serious or continuing noncompliance with the PHS Policy or serious deviations from the provisions of the Guide]

⁹ [In addition to PHS requirements for IACUC review/application for funding, USDA regulations require]: 2.31(d)(1)(ii) - "The principal investigator (PI) consider alternatives to procedures that cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources...used to determine that alternatives were not available."

¹⁰ 2.33(a)(1) - "In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility." [USDA requirement additional]

¹¹ 2.32(c) - "Humane methods of animal maintenance and experimentation, including the basic needs of each species, proper handling and care for the various species of animals used by the facility, proper pre-procedural and post-procedural care of animals, and aseptic surgical methods and procedures."

¹² 2.32(c) - additional specifications include:

^{- &}quot; proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility"

^{- &}quot; methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility..."

- "utilization of services (e.g. National Agricultural Library, National Library of Medicine) to provide information on appropriate animal care and use, alternatives to the use of live animals in research, that could prevent unintended and unnecessary duplication of research involving animals, and regarding the intent and requirements of the Act." [USDA training specifications are more detailed than PHS Policy].
- ¹³ 2.31(d)(iv)(C) " Procedures that may cause more than momentary or slight pain or distress to the animals will...not include the use of paralytics without anesthesia."
- ¹⁴ Part 3 Subpart A 3.6(c)(1) "Each dog housed in a primary enclosure must be provided with a minimum amount of floor space, calculated as follows: (length of dog in inches + 6)² /144 = required floor space in square feet).
- Part 3 Subpart D 3.80 (b) "Primary enclosures [for nonhuman primates] must meet the minimum space requirements provided in this subpart."
- In situations where the USDA regulations and the Guide differ with respect to space requirements, the larger of the two must be followed.
- ¹⁵ Part 3 Subpart A 3.8 " ...research facilities must develop, document, and follow an appropriate plan to provide dogs with the opportunity for exercise. In addition the plan must be approved by the attending veterinarian. The plan must provide written standard procedures..."
- ¹⁶ Part 3 Subpart D 3.81 " ...research facilities must develop, document, and follow an appropriate plan for environment enhancement adequate to promote the psychological well-being of nonhuman primates."

Arkansas State University Institutional Animal Care and Use Committee

To: Dr. Michael Dockter

Associate Vice Chancellor for Research and Technology Transfer

From: Kris Biondolillo, IACUC Chair

Re: Semiannual Program and Facility Review and Evaluation

Date: January 13, 2010

The IACUC has completed its second semiannual review of the program and facilities for the 1/01/09-12/31/09 reporting period as required by the PHS Policy on Humane Care and Use of Laboratory and as a condition of this institution's Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW). The report of the review, conducted on January 07, 2010, is attached.

Evaluation of Program:

There were no deficiencies in the areas of Institutional Policies and Responsibilities.

Improvements have been made in the documentation of and access to training of personnel involved directly or indirectly with the program. Expanded and more specialized training opportunities are now in place.

Improved procedures for providing protocol review decisions are in place with PIs receiving a form electronically indicating protocol approval and assigned protocol number. A hard copy form follows with the IACUC chair's signature.

There were no deficiencies identified in the areas of Veterinary Medical Care.

There were minor deficiencies in the areas of Animal Housing and Support Areas. They are identified in the report of the review. Anthony McMickle (ABI facility) and Kris Biondolillo (Psychology facility) have corrected them.

There were no minority views.

Signatures:

Kris Brondo lillo, Chair MPBNIL 1/13/2010

Anne A. Grippo, Member and allog 1-13-2010

Malathi Sivatsa-, Member 1-13-2010

from & Bern, Member 1-13-2010

Anton P. Martin 1-13-2010

ATTACHMENT D DELEGATION OF AUTHORITY



P.O. Box 179 State University, AR 72467

> Phone: 870-972-2030

Fax

870-972-2036

www.astate.edu

Jonesboro, Arkansas

Dr. Glen Jones Senior Associate Vice Chancellor for Academic Affairs and Research Arkansas State University PO Box 179 State University, AR 72467

Dear Dr. Jones:

May 7, 2010

Effective July 1, 2010, when I become the Interim Chancellor and you assume responsibility as Interim Provost, I delegate responsibility for campus-wide animal care and use to you. Your appointment in this role will continue as long as you are in the Provost's position.

Should you have any questions, please let me know.

Warmest regards,

G. Daniel Howard, Ph.D.

Executive Vice Chancellor and Provost

S. Samestoward



May 25, 2010

P.O. Box 2760 State University, AR 72467-2760

Re: Federal Assurance

Phone:

870-972-2694

Ladies and Gentlemen:

870-972-2336

Please note the following corrections/updates to our Assurance of May 21, 2010.

www.astate.edu

1. Appoint the IACUC.

Part III.C. reads in part, "The Chancellor has delegated to the <u>Institutional Official</u> the authority to appoint the members of the IACUC. In accordance with the Health Research Extension Act of 1985, this delegation of authority is specific and is in writing."

These sentences should read as follows: "The Chancellor has delegated to the <u>Provost</u> the authority to appoint the members of the IACUC. In accordance with the Health Research Extension Act of 1985, this delegation of authority is specific and is in writing."

2. Reports of IACUC Evaluations.

Henceforth, for its reports of its evaluations (program reviews and facilities inspections) the IACUC will use the OLAW Semiannual Report to the Institutional Official sample format.

3. Attachment D.

Please disregard Attachment D to the Assurance; I am, and will remain for the foreseeable future, the Institutional Official [for animal care and use] at Arkansas State University. As such, I report to the Provost who, in-turn, reports to the Chancellor. Should this situation change, I and/or my replacement will promptly notify OLAW.

Best regards,

Michael E. Dockter, Ph.D.

Associate Vice Chancellor for Research and Institutional Official