

## University of Arkansas, Fayetteville

### Assurance of Compliance with Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (#A3878-01)

The University of Arkansas, Fayetteville, hereinafter referred to as Institution, hereby gives assurance that it will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

#### I. Applicability

This Assurance is applicable to all research, research training, experimentation, and biological testing and related activities, herein-after 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 sub-granting or subcontracting of a PHS-conducted or supported activity by this institution. "Institution" includes the following branches and major components of The University of Arkansas, Fayetteville:

College of Education

College of Engineering

Dale Bumpers College of Agricultural, Food and Life Sciences

J. William Fulbright College of Arts and Sciences

#### II. Institutional Policy

- 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 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 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:

See Attachment #1 for organizational chart.

In summary, the Institutional Official responsible for the animal care and use program is the Vice-Chancellor for Academic Affairs and Provost (Provost). The Director of Research Support and Sponsored Programs (Director), who reports to the Provost through the Vice Provost for Research (VP), provides administrative support to the IACUC, and is responsible for the oversight of the Central Laboratory Animal Facility (CLAF). The Laboratory Animal Veterinarian reports to the Director. Day-to-day operation of the CLAF, along with IACUC record-keeping, is the responsibility of the CLAF Manager, who reports to the Director.

- B. The Laboratory Animal Veterinarian (also referred to by the Institution as the Animal Welfare Veterinarian) has a 25% appointment and reports to the Director of the office of Research Support and Sponsored Programs (RSSP). The qualifications (Attachment #2), functions and responsibilities of the veterinarian who will participate in the program are as follows:

1. Implement and monitor institutional compliance with guidelines for the care and use of animals.
2. Assist in the technical review of research protocols with respect to veterinary care, animal husbandry and animal welfare.
3. Serve as a standing, voting member of the Institutional Animal Care and Use Committee.
4. Consult with investigators and advise, through the IACUC, or if necessary, directly through the Provost, the details of laboratory animal care.
5. Assist in the periodic inspection of laboratory facilities and animals.
6. Assist in surgery programs and post-surgical care procedures as needed.
7. Veterinary Care of Laboratory Animals:  
Provide assistance in the care of sick or injured animals along with veterinarians (who are duly licenced) on the faculty of the Poultry Science Department. Poultry Science Laboratories will provide backup support in diagnosis and treatment. Care will also be provided by private practitioners as required. Animal Science and Guide users regarding handling, immobilization, anesthesia, analgesia and euthanasia procedures through the review of protocols by the IACUC and by the

laboratory animal veterinarian. Outside specialists will be utilized when needed. When the Laboratory Animal Veterinarian is not available, the Division of Agriculture's Extension Veterinarian (who is duly licenced) answers emergency calls for the CLAF, which is the primary facility in which common laboratory species are housed and cared for. The Laboratory Animal Veterinarian has complete authority to require the cessation of any activity that results in undue stress or injury to animals, especially as a result of procedures that have not been approved by the IACUC or as a result of of improperly trained personnel.

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 program, facilities, and procedures. The IACUC consists of at least five members Its membership meets the compositional requirements set forth in the PHS Policy at IV.A.3.b. Attached (Attachment #3) is a list of the names, position titles, earned degrees and other credentials of the IACUC chairperson and members.

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.
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. At the time of inspection, all minor deficiencies which can be corrected in the inspectors' presence will be corrected immediately. For those deficiencies which cannot be corrected immediately, the IACUC Chair or his/her designee will contact the responsible investigator to agree upon a reasonable and specific plan and schedule for correction of the deficiency. All reports will differentiate between major and minor deficiencies and indicate that the deficiency 1) has been corrected, or 2) include a reasonable and specific plan and schedule for correcting each deficiency not corrected at the time of the inspection.

Correction of all deficiencies will be confirmed by the IACUC Chair or his/her designee.

The semi-annual report will contain any minority views expressed by Committee members or, in the event that no minority views are expressed, so state.

3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy at IV.B.3. and submit the reports to the Provost.
4. Review concerns involving the care and use of animals at the institution. The intent of IACUC is to handle all complaints as expeditiously and appropriately as possible. All serious infractions will be referred for resolution under the Institution's Research and Scholarly Misconduct Policies and Procedures.

It will be included in the Institution's Policy on the Use of Animals in Research, and stated in the IACUC's Policies and Procedures, that any individual, whether or not an employee of the Institution, may submit concerns or complaints about the use, care, or handling of animals to the following individuals: the IACUC Chair, the IACUC Program Manager (who is also the Manager of the Central Laboratory Animal Facility), or the Director of the Office of Research Support and Sponsored Programs. Either the Chair or his/her designee will initiate an investigation of the charges via informal discussion, observation, or other reasonable means to 1) resolve minor issues to the satisfaction of all parties or, 2) determine if the complaint merits referral to the Vice Chancellor of Academic Affairs (VCAA). Upon receipt of the referral by the IACUC Chair, the VCAA will follow the procedures outlined in the Institution's Research And Scholarly Misconduct Policies And Procedures. In addition, the project may be suspended as described in Part III.D.10, below.

5. Make written recommendations to the Provost regarding any aspect of the institution's animal program, facilities, or personnel training. The report will include violations, deficiencies, and deviations from approved practices.
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. Requests for modification(s) to an approved protocol are reviewed in the same fashion as new protocols. The process is described in III.D.7, below.
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. A summary of the protocol review process is as follows:

If a protocol is to be reviewed at a scheduled meeting, the protocol is distributed to all Committee members at least five (5) working days prior to the meeting. There are no primary or secondary reviewers assigned. At the meeting, the protocol is discussed and action is voted upon. One of four (4) outcomes will occur:

- 1) Disapproval - This outcome is usually the result of the investigator submitting a protocol that provides insufficient information for members to evaluate it or it contains information or description of procedures which the Committee feels that it cannot approve. A "Protocol Disapproved" notice is sent to the investigator informing him/her of the outcome of the review. The disapproval notice contains the reasons for disapproval and suggestions that might result in approval if the investigator wishes to submit a new protocol. If the investigator wishes to pursue approval of the activity, a new protocol (with new number assigned) is required.

2) Revise and resubmit - In this case the Committee understands the rationale and objectives of the proposed research. However, either insufficient information is provided for the IACUC to make a determination or the protocol is written in an unclear manner and significant revision of the protocol is required to document compliance with regulations and policies. An “IACUC Action Notice” is sent asking the investigator to revise and resubmit the protocol. This Notice lists the protocol deficiencies which must be addressed. Depending on the degree of revision required and the seriousness of the issues (e.g., typographical errors, a change in the number of animals to be used, unacceptable method of euthanasia) the investigator is advised that the revised protocol will be reviewed at the next scheduled meeting or, if deemed appropriate, will undergo Designated Member (Expedited) Review Method.

3) Approved contingent upon information/clarification - This is considered to be an approval. The Committee determines that the information provided in the protocol is sufficient to allow evaluation and approval, but that minor administrative issues require additional information or clarification. The Investigator is notified via email. Once the information is received from the Investigator, the Chair or his/her designee reviews the information. If the response is complete and satisfactory, the reviewer signs and dates it indicating approval. The approved correspondence is sent to the Program Manager who then sends out the approval notice.

4) Approved - A majority of the members at the meeting vote to approve as written. The Program Manager sends a written approval notice.

Where there are extenuating circumstances, such as an impending sponsor deadline, sponsor required changes in an existing protocol, or the required date for approval precedes the date of the next scheduled IACUC meeting, the IACUC chair may route the protocol for review by the Designated Member (Expedited) Review process. The Chair will designate an IACUC member who has the expertise to evaluate the project and the Laboratory Animal Veterinarian as reviewers. The protocol will also be distributed to the members of IACUC. Members have seven days in which to communicate questions or concerns or to call for full review at a properly convened meeting. Outcomes of a review by the Designated Member Review process are the same as those for a full IACUC review.

8. Notify investigators and the institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy at IV.C.4. To date, the IO has not been directly informed of individual protocol/modification determinations. Instead, access to results of the reviews has been made readily available upon request by the IO. We recently initiated a

procedure to send copies of the monthly meeting agenda (which is the vehicle by which IACUC members are informed of the results of protocols and requests for modification that are reviewed by Expedited Review (the Designated Member Review Method), and the meeting minutes which include the protocols reviewed at the meeting and the outcome of such review directly to the IO.

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 at IV.C. 1-4 at least every three years. By Institutional Policy, all protocols are required to be resubmitted at the end of 3 years if the project is to be continued.
10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6. The IACUC may suspend any previously approved activity if it determines that the activity is not being conducted in accordance with an approved protocol, applicable provisions of the Animal Welfare Act, the Public Health Service Policy on Humane Care and Use of Laboratory Animals, the OLAW Institutional Animal Care and Use Committee Guidebook, and/or the institution's Animal Welfare Assurance. The investigative process will include referral to the Institution's Committee on Research Misconduct as described in Part III D. 4 (and as expanded here).

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. A suspension will not occur prior to consultation with the responsible individual (that person in charge of the activity). Such consultation will allow the responsible individual to be informed of the cause for concern so that an opportunity is afforded to explain their side of the issue. If the IACUC suspends an activity involving animals, 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 the PHS Office of Laboratory Animal Welfare (OLAW), the Animal and Plant Health Inspection Service (APHIS), USDA, and/or any other Federal agency funding that activity. The issue may also be referred to the VCAA for investigation as potential research misconduct.

If the IACUC Chair and the Laboratory Animal Veterinarian determine that there is immediate and significant danger to the health and welfare of research animals or personnel, the Chair will issue an immediate, temporary suspension and require such action as necessary to address the immediate concerns. The matter will then be referred to the full IACUC for review and resolution as described above.

The procedures which the IACUC will follow to fulfill the requirements set forth in the PHS Policy at IV.B. are as follows: (See Attachment #4 for IACUC Procedures and Protocol Form)

The University of Arkansas IACUC is scheduled to meet once monthly, usually on the first Friday of each month. A subcommittee of at least two IACUC members conducts inspections of animal facilities twice per year (June and December). A summary of the inspection noting deficiencies and recommended procedures for correction is presented to a meeting of the full committee. The Institutional program is also reviewed by a quorum of the committee at the time of the semi-annual inspections. The program is reviewed to insure compliance with appropriate regulations including PHS policy, the Animal Welfare Act, the Institutional Assurance, and the Institutional Policy for the Use of Animals in Research and Teaching. Following majority approval of the program review, and the facilities inspections, the report is signed by a majority of committee members and forwarded to the office of RSSP from which the report is submitted to the Provost.

Protocol review procedures:

1. Investigators must submit protocols to the IACUC Program Manager (RSSP) no later than 7 working days prior to the next scheduled committee meeting.
2. The Program Manager makes full copies of the submitted protocols and distributes them to the IACUC members.
3. Committee approval of a protocol requires that a quorum (50% plus 1) of the committee be present for the review. At the meeting, members' concerns/questions are discussed, and any recommendations for change are noted. Protocols may be approved without modification, approved subject to receipt of verification of requested changes by the IACUC Chair, or a request may be made for additional information from the principal investigator and action on the protocol will be deferred until the next meeting or until the needed information is submitted. A principal investigator may, at the request of the committee, be asked to appear before the committee to answer specific questions. Approval is by majority of the convened quorum.
4. If for some reason a protocol cannot be reviewed in a timely fashion at a convened meeting, an expedited review procedure is available to the investigator. For this review process, the Chair (or Program Manager) designates that the protocol be reviewed by the Laboratory Animal Veterinarian and an IACUC member who has the expertise to evaluate the protocol. In addition, a copy of the entire protocol is distributed to the remaining members. The members have seven days in which to communicate questions/concerns to the Chair or designated reviewers, or to call for full review at a convened meeting. If there is no response from the committee members within this period, the two appointed reviewers have the authority to approve the protocol for the committee. Approval cannot be denied via the expedited review process. If either reviewer feels that he/she cannot approve the protocol in question, the protocol must be given full review at a convened meeting where a quorum of IACUC members are present. Generally only protocols that contain procedures that have been thoroughly

reviewed in the past or contain procedures that subject the animals to no or very minimal stress are allowed to be reviewed by expedited review.

In the review of a proposal, the IACUC shall determine that the components of the research project related to the care and use of animals conforms with the Institution's 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 sacrificed 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 facility manager, or other professional 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 recommendations of the most recent edition of the American Veterinary Medical Association (AVMA) Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.
5. Protocols are approved for a maximum of 3 years and subjected to an Annual Review, consistent with the requirements of the Animal Welfare Act (Annual Review form is found as Attachment #5). In lieu of continuing review of a protocol for studies that are longer than 3 years, the IACUC requires that a new protocol be submitted. Notice of approval of a protocol is made in writing to the principal investigator, the Laboratory Animal Veterinarian, and for Arkansas Agricultural Experiment Station projects, to the Vice-President for Agriculture.

6. 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 PHS Policy. The IACUC will 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.
  7. If the IACUC suspends an activity involving animals, 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.
  8. Significant changes in an approved protocol must be reviewed and approved by the IACUC prior to initiation of such changes.
  9. The document entitled "Research Misconduct Policies and Procedures" that was prepared by the University of Arkansas, Fayetteville in FY 1990 has been approved by IACUC as a vehicle to be used by employees or individuals to report deficiencies in animal care and treatment and bring charges of animal care misconduct (Attachment #6).
- E. The individual(s) authorized by this institution to verify IACUC approval of those sections of applications and proposals related to the care and use of animals is the Provost
- F. The health and safety program for personnel who work in laboratory animal facilities or have frequent contact with animals is follows: Laboratory and Animal Care employees must complete two basic safety courses provided by the Office of Environmental Health and Safety. They are: 1) Occupational Safety Training — a course designed to provide information about and to promote awareness of potential hazards in the work environment as well as provide information regarding faulty or unsafe work practice; and 2) Campus Safety Training — a course which addresses such topics as ergonomics, fall prevention, forklift safety, personal protective equipment, sound surveys and noise abatement, heat stress prevention, defensive driving, power tool safety, electric safety, air quality, confined space entry, safety audits, and OSHA training. Safe care and handling techniques will be demonstrated by the principal investigator and/or the Facility Manager. Caretakers will not be allowed to handle animals unsupervised until they have demonstrated proficiency in the applicable skills. Animal caretakers are notified prior to the initiation of research if an activity will include the use of an agent that is infectious to human beings. The animal caretaker is instructed by the principal investigator and/or the Facility Manager in methodology to prevent contact with the agent and subsequent infection. Such instruction must be given and documented prior to the employee handling research animals or equipment or performing facility and animal maintenance. Where prophylactic vaccination/immunization is indicated, it will be offered to the employee at no cost. Refusals of vaccination/ immunization must documented in writing. This

institution does not use or house nonhuman primates, dogs, or cats. In case of animal bites, scratches, allergies, or other work-related injuries/illness, the University has a fully compliant Worker's Compensation/On-the-Job Injury program. Urgent and Emergency assistance is available on a 24-hour, 7 days a week basis. Non-urgent care is available from 7:00 AM — 6:00 PM Monday through Friday and Saturdays from 9:00 AM to Noon. Information and training in the area of zoonoses is available to all investigators and personnel with significant contact with animals..

- 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, by species, of animals in each facility are as follows:

It is University of Arkansas Policy that all research (and teaching) projects using live warm-blooded vertebrate animals, except those studies which involve food and fiber research and require domestic farm species to be housed in an agricultural setting, will be housed in the Central Laboratory Animal Facility (CLAF). In cases where there are legitimate circumstances under which experiments using animals must be conducted in areas other than the CLAF, the location and rationale for use must be approved by the IACUC prior to beginning such activities.

Currently there are two approved animal housing areas in addition to the CLAF. One facility, of approximately 1200 square feet, has an average population of 20 animals when studies are being conducted. This facility is located within Memorial Hall. It is used by one investigator from the Psychology Department. The other approved facility is located in the Poultry Science Building on the 4th floor; occupies approximately 900 square feet, and is used for housing poultry, that, because of the need for frequent observation, biological status, surgical manipulation, etc., cannot be housed in the farm facilities. When a study is in progress, the daily average population has been about 6 birds.

The CLAF (9295 sq.ft) contains 13 animal holding rooms. There are three large and eight smaller rooms of the same design, a room with four cubicles, and a quarantine room which is of the same design as the regular animal rooms, but on a smaller scale. All animal holding rooms allow for individual control of temperature and lighting cycles and provide the recommended ventilation rates. There is also procedure and laboratory space, an area for aseptic surgery, and support areas for this function. Specialized support areas that allow for the proper sanitization of animal caging and for the storage of clean equipment, animal feed and bedding are also included within the facility. Mice, rats, hamsters and Japanese quail are the only species that have been housed within the facility since it has been put into operation (February 2000).

Average daily population:

Rats - Rats have not been used for some time, but for an experiment that had been conducted since the submission of the last Assurance, 6 animals was the average daily population.

Mice - 611

Hamsters - 36

Quail - There is one class project, conducted biannually year, that houses 16 quail for a 30 day period.

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

The training, instruction, and qualifications of scientists, and students are assessed in the review of protocols by the IACUC. Vitae with the experience and qualifications for all individuals with significant involvement in the care or use of animals used in approved protocols is maintained by the facility Manager who is also the IACUC Program Manager.

Scientists, animal technicians, and other personnel using animals are trained by the personnel in charge of the animal facility they are using. Students (graduate and undergraduate) are instructed and supervised in proper techniques, handling and use by the principal investigator in charge of the project. New techniques and procedures with which a principal investigator is unfamiliar are taught by other scientists with expertise in the area or by a qualified veterinarian.

The CLAF Manager, who has a Bachelor's Degree in Laboratory Animal Science, is an AALAS certified Laboratory Animal Technologist, and has more than 30 years experience in the field of animal facility management, has the responsibility of assuring that the animal caretakers are trained in humane care and use of animals; this is accomplished by on-the-job training.

The institution will provide training/instruction to scientists, animal technicians and other personnel involved in animal care, treatment or use to minimize the numbers of animals required to obtain valid results and minimize distress. Further, the protocol form requires the investigator to acknowledge that unnecessary or excessive use of animals has been addressed. (See page 6 of the protocol form.)

#### IV. Institutional Status

As specified in the PHS Policy at IV.A.2, as Category 2, all 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. The report of the IACUC evaluation is submitted to the Provost. A copy of the report is attached. [See

Attachment #7 for most recent report]. The report describes the nature and extent of this institution's adherence to the Guide. Any departures from the Guide are identified specifically and reasons for each departure must be justified. Where program or facility deficiencies are noted, the report contains a reasonable and specific plan and schedule for correcting each deficiency. The report distinguishes significant deficiencies from minor deficiencies. Semiannual reports of the IACUC evaluation submitted to the Institutional Official, the Provost.

## 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 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.
  - 4. Records of semiannual IACUC reports and recommendations as forwarded to the Provost. All semi-annual reports and recommendations to the Provost will include minority views regarding reports and recommendations. If there are no minority views, the report or recommendation will so state.
  - 5. Records of inspections by and annual reports to APHIS.
- 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. At least once every 12 months, the IACUC, through the Institutional Official, will report in writing to the Office of Laboratory Animal Welfare (OLAW):
  - 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 IACUC membership. If there are no changes to report, this institution will submit a letter to OLAW stating that there are no changes.

2. Notification of the date that the IACUC conducted its semiannual evaluations of the institution's program and facilities (including satellite facilities) and submitted the evaluations to the Provost.
- B. The IACUC, through the Institutional Official, will provide the OLAW and APHIS promptly 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 VI.A.2. and VI.B. above shall include any minority views filed by members of the IACUC.

## VII. Institutional Endorsement and PHS Approval

### A. Authorized Institutional Official

Name: Bob Smith  
Title: Vice Chancellor for Academic Affairs and Provost  
Address: University of Arkansas  
ADMIN 422  
Fayetteville, AR 72701

Phone: (479) 575-2151

Fax: (479) 575-7076

Signature:

### B. PHS Approving Official

Name:  
Title:  
Address: Office of Laboratory Animal Welfare  
Division of Assurances  
6705 Rockledge Drive  
RKL1, Suite 1050, MSC 7982  
Bethesda, MD 20892-7982  
  
(Express Mail Zip 20817)

Phone:

Fax:

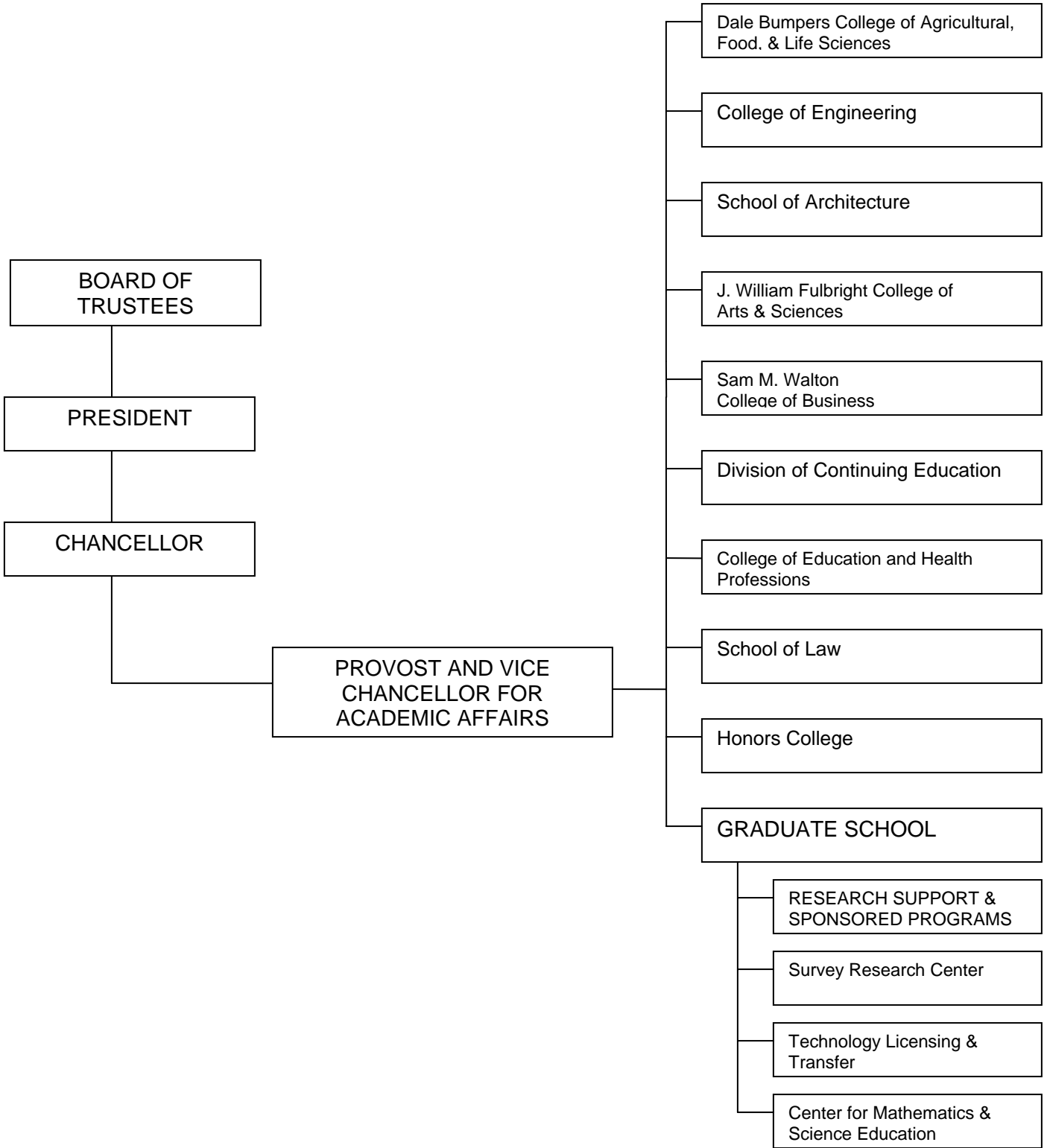
Signature:

Date:

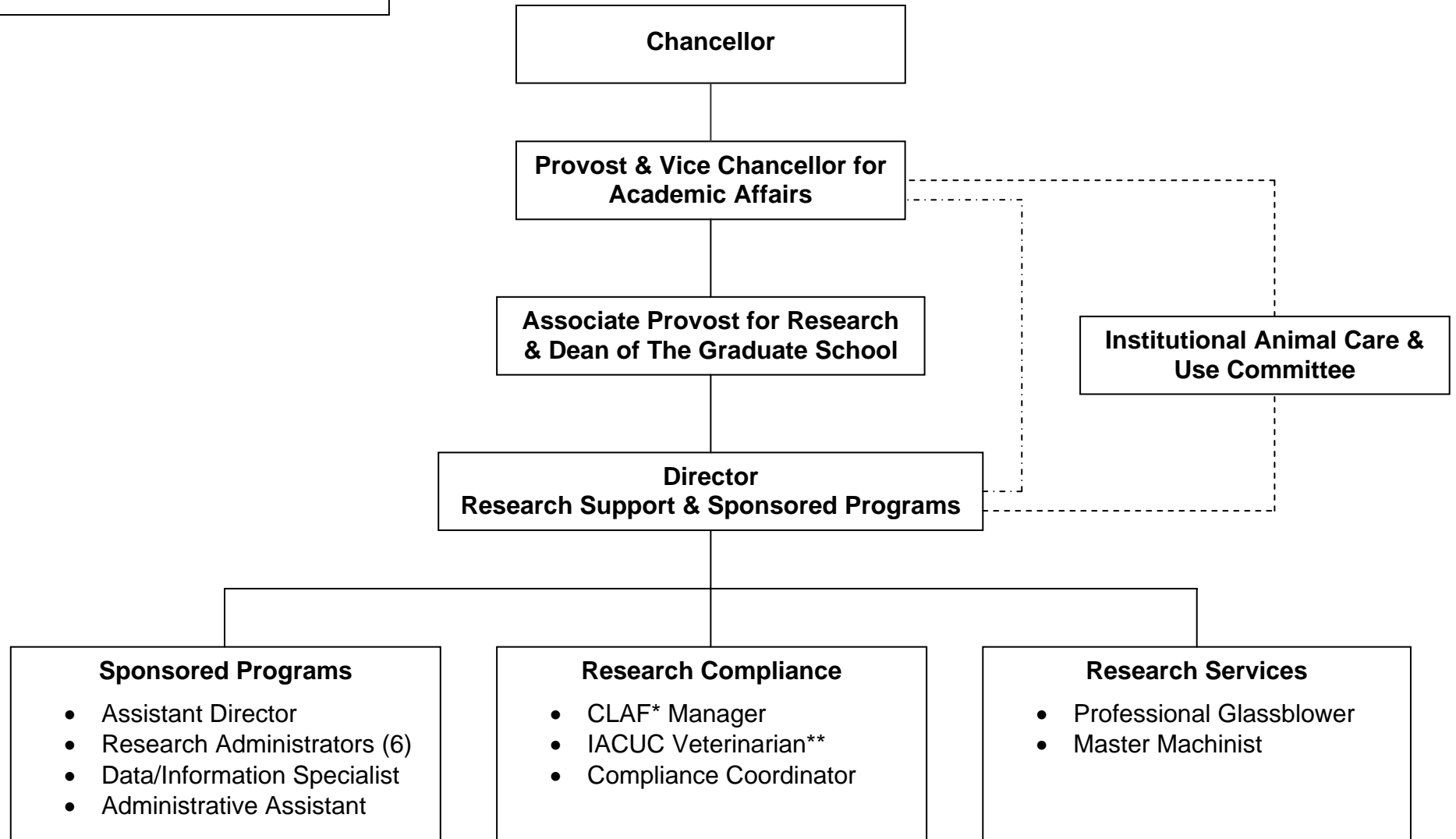
### C. Effective Date of Assurance

### D. Expiration Date of Assurance

**Attachment 1A**



**ATTACHMENT 1B**



\*CLAF = Central Laboratory Animal Facility

\*\*Veterinarian has direct access to the Vice Chancellor for Academic Affairs as previously noted.

ATTACHMENT #2  
ANIMAL WELFARE VETERINARIAN (25%)

Richard K. Fulton, D.V.M., M.S.  
1650 Taldo Loop  
Springdale, AR 72762

(479) 361-2617

**Education:**

M.S., Reproductive Physiology, Colorado State University (1974)  
*Emphasis on Bovine Estrus Synchronizaton*

D.V.M., Veterinary Medicine, Colorado State University (1964)

B.A., Social Sciences, University of Phillipines (1957)

**Professional Experience:**

Research veterinarian experienced in conducting and monitoring research trials for both a major pharmaceutical company and the University of Arkansas with over 25 years diverse experience in veterinary medicine and research. International and domestic experience in veterinary medicine and research involving both domestic livestock and laboratory animals. Special knowledge in ecto-and endo-parasite research of food and companion animals.

University of Arkansas (1996-present)

*Laboratory Animal Veterinarian* - Responsibilities include: Monitor and advise research trials conducted within the Central Laboratory Animal Facility; serve as Animal Welfare Veterinarian for the IACUC and participate in all of the required functions of this committee.

For additional training in Laboratory Animal Science, attended the 1996 National AALAS meeting.

Merck & Co., Springdale, AR (1975-1995)

*Assistant Director of Field Operations* (1982-1995) - Organized and monitored research trials with outside cooperators and conducted in-house research studies at the Arkansas Research Farm, along with supervising four employees (biologists). Assisted farm director in administrative functions. Accomplishments include:

- Served as Chairman of the Arkansas Research Farm IACUC for 5 years. Conducted on-farm inspections and worked with the Merck IACUC to keep research facility in compliance with all pertinent regulations.

- Supervised and monitored research studies involving common laboratory animal species for both in-house and with outside contract investigators involved with the development of animal health products.
- Completed each year from 20 to 35 final reports of developmental studies to support FDA licenses.
- Organized, developed and trained personnel to successfully operate a cattle horn fly colony and testing facility.
- Saved the company approximately \$100,000 by determining that an organophosphate compound was responsible for the deaths of several purebred cattle rather than Ivomec<sup>®</sup>, resulting in continued marketing of Ivomec<sup>®</sup>.

*Assistant Director of Clinical Research, Canyon, TX ( 1977-1982) - Organized and monitored research trials with outside cooperators. Worked independently to monitor research studies for the development of Ivomec<sup>®</sup> (cattle anthelmintic).*

*Technical Services Veterinarian, Merck Animal Health Division, Canyon, TX (1977-1982) - Supported marketing by assisting in meetings to educate users and promote products and followed up on product complaints. Also assisted with in-line product demonstration trials.*

Veterinary Consultant, Yuma, AZ (1974-1975) - Consultant for five feed yards; organized and directed feed lot health programs.

Resident Veterinarian, McElhaney Cattle, Co., Yuma, AZ (1971-1974)

Veterinary Private Practice, Gisborne and Tirau, New Zealand (1964-1975)

### **Academic Experience:**

Clinical Instructor, University of Queensland (1968-1969)

### **Professional Memberships:**

American Association for Laboratory Animal Sciences  
 American Veterinary Medical Association  
 Northwest Arkansas Veterinary Medical Association  
 American Association of Bovine Practitioners  
 Arkansas Cattleman's Association  
 American Society of Animal Science

ATTACHMENT #3

**MEMBERSHIP OF THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE**

July 1, 2004 - June 30, 2005

NAME OF INSTITUTION: University of Arkansas

ASSURANCE NUMBER: A3878-01

<b>Chairperson Name, Title, and Degree/Credentials</b>	<b>Business Address, Phone, Fax, and Email of Chairperson</b>
Name: John D. Kirby	Address: Poultry Science Building, 409 University of Arkansas Fayetteville, AR 72701
Title: Professor	
Degree/credentials: PhD, Poultry Science	Phone: (479) 575-8623 Fax: (479) 575-3026 Email: jkirby@.uark.edu

<b>Name of Member</b>	<b>Degree/Credentials</b>	<b>Position Title</b>	<b>PHS Policy Membership Requirements</b>
Richard K. Fulton	D.V.M., M.S.	Animal Welfare Veterinarian	Direct program responsibility
Jill Hatfield		Supervisor of Fayetteville Animal Services	non-affiliated member
Jason Apple	PhD/ Animal Science	Associate Professor	Scientist
Michelle King	M.S. Library Science	Associate Librarian	Non-scientist
Casey Owens	PhD/Poultry Science	Assistant Professor	Scientist
Charles Riggs, Jr.	PhD/Health Science, Kinesiology, Recreation & Dance	Professor	Scientist
Jeff Stripling	PhD/Psychology	Professor	Scientist
David McNabb	PhD/Biological Sciences	Assistant Professor	Scientist
Jeremy Devers		Graduate Student	Scientist
Rosemary Ruff	Director of Research Support and Sponsored Programs (RSSP)	( <i>ex officio</i> ) member	Non-voting
Carol Rodlun	B.S., LATG	Program Manager, CLAF Manager	Non-voting

## Attachment #4

### Procedures for Approval of Animal Use Institutional Animal Care and Use Committee University of Arkansas, Fayetteville

The Institutional Animal Care and Use Committee (IACUC) at the University of Arkansas, Fayetteville (hereafter referred to as the University) supports the responsible use of animals in research and teaching. All animal use covered by the University's Policy on Animal Care and Use, except standard agricultural teaching applications, requires written approval, from the IACUC, of an Animal Use Protocol submitted by the user for review by the committee. Activities that require an Animal Use Protocol include all research and teaching using live vertebrate animals, except standard agricultural teaching applications, that is 1) conducted at the University campus, or by University faculty, staff, or students when acting as representatives of the University at off-campus locations, or 2) conducted at the Agricultural Experiment Station, or by individuals acting as representatives of the Agricultural Experiment Station at off-site locations. Written approval of an Animal Use Protocol by the IACUC must be received by the user before ordering animals from a licensed supplier or beginning the proposed work. Animal Use Protocols are not required for services provided by the Cooperative Extension Service of the University of Arkansas Division of Agriculture.

This review process serves a number of distinct purposes. These are 1) to ensure that all animal use at the University is conducted in a humane and responsible fashion; 2) to ensure compliance with the appropriate federal and state laws and regulations; 3) to ensure compliance with the University's Policy on Animal Care and Use, 4) to ensure that the University has a written record of all animal use in progress on this campus; and 5) to protect the principal investigator of each Animal Use Protocol by documenting in writing that the protocol he/she is following has been approved and endorsed by the University.

The process for gaining approval for an Animal Use Protocol is outlined below:

1. All research and teaching that uses live vertebrate animals and meets the conditions outlined above requires an Animal Use Protocol. This applies to work with animals done by a faculty member, post-doc, staff member, graduate student, undergraduate student, or any other representative of the University. However, regardless of who actually does the work, the Principal Investigator (PI) who signs the Animal Use Protocol and accepts responsibility for the oversight and proper conduct of the approved work must normally be a full-time faculty member at the University. The IACUC will consider exceptions to this rule on a case-by-case basis if unusual circumstances make it impractical for a faculty member to serve as PI.
2. As indicated above, research and teaching conducted at off-campus locations requires an Animal Use Protocol only when it is conducted by University faculty, staff, or students acting as representatives of the University. Examples of off-campus activities that would require an Animal Use Protocol include 1) a student

collecting data off-campus that is required for an independent research project, honors's thesis, Master's thesis, or Doctoral dissertation, or 2) a faculty member doing contract work through the University with a private company at that company's facilities. However, a faculty member doing consulting work off-campus on his/her own time and acting as a private individual would not need to submit an Animal Use Protocol. In addition, an Animal Use Protocol need not be submitted in cases where a faculty member or other representative of the University plans to participate in a project in which all animal procurement, housing, and use will take place at another university or research institution, provided that a protocol describing the project has been approved by that institution's IACUC.

3. Plan ahead. The IACUC currently meets once per month, so it may take several weeks after submission of a protocol for you to receive written approval. Please note that you cannot commence work on a project or order animals for that project until you have received written approval of your protocol from the IACUC. To ensure review at the next regularly scheduled IACUC meeting, a protocol should be received by the Office of Research Support and Sponsored Programs (RSSP) at least seven working days prior to the meeting. If you are on a short time-line, please request an expedited review from the Chair (or Program Manager) of the IACUC.
4. Obtain an Animal Use Protocol form. This can be done in several ways:
  - A. By campus mail. Contact the IACUC Program Manager (Carol Rodlun) at AFLS A-42; 575-2994.
  - B. By e-mail. Request a file containing the protocol form from Program Manager; [crodlun@uark.edu](mailto:crodlun@uark.edu).
  - C. By downloading the appropriate computer files from the IACUC's home page on the World Wide Web [<http://www.uark.edu/admin/rsspinfo/compliance/animal-subjects/index.html>]
5. Plan your protocol to conform to the relevant regulations (see Item 3 of the University's Policy on Animal Care and Use). Determine which category your protocol falls under, and if necessary request a copy of the relevant regulations for your protocol from the Program Manager. Copies of all regulations are available for your inspection. In most cases the category to which a protocol belongs will be obvious. If you are uncertain about how the University's Policy on Animal Care and Use applies to your project (e.g., which category of regulations applies to your project), we encourage you to seek advice from the Chair of the IACUC before submitting a protocol. At the time the IACUC reviews your protocol, it will make an official assignment of your protocol to a category. In case of a disagreement regarding classification, the IACUC, by majority vote, will have the final say regarding which category applies to a specific Animal Use Protocol.
6. You can save a substantial amount of effort by planning ahead and submitting a single protocol for a series of related projects that use similar methods (e.g., for a

series of experiments in an extramural grant proposal, for the same instructional procedure used in repeated offerings of the same course, etc.).

7. Fill out an Animal Use Protocol form [**verify that you have the most recent version**] and submit it to IACUC Program Manager (Carol Rodlun), AFLS A-42. The form may be completed with a typewriter on a paper copy or with a word processor using a downloaded computer file, but in either case one paper copy should be submitted (computer file of the completed form can be attached to an e-mail, but hard copies of the signature page(s) need to be sent to the Program Manager).

The form has been designed with several separate parts to streamline both the writing and the review of the protocol. These parts are described below.

- A. Cover Sheet  
Required of all projects. This lists the title of the project, the personnel involved, and the animals to be used.
- B. Checklist  
Required of all projects. This previews the project for the committee, allowing easy identification of the items requiring close attention in the narrative portion. Note that it does not substitute for the narrative portion of the protocol in any way. Careful completion of the checklist will help expedite your review.
- C. Narrative  
Required of all projects. This is a narrative description of the project. It should stand alone and not require referral back to the checklist. It should cover all methods and procedures involving the use of animals in order to make the project comprehensible to members of the committee. The level of detail required for each particular procedure will vary with the expected impact of that procedure on the well-being of the animals being used.  
**Please follow instructions for each part and understand that failure to provide sufficient details as to experimental design and procedures may result in the protocol being disapproved.**
- D. Assurance Statements  
Required for biomedical research and teaching only. This meets the reporting requirements specified in the NIH Guide and the Animal Welfare Act regulations.

The Animal Use Protocol should be filled out with care and attention to detail. Please note that under the Freedom of Information Act your entire protocol could become public, and it is in your own best interest to present a complete, accurate, and cogent description of your research and the rationale behind it.

8. Regular IACUC review of your protocol will occur at the first regularly scheduled meeting occurring at least one week after submission of your protocol. Protocol review requires that a quorum be present (greater than 50% of the voting members). IACUC members participating in a protocol cannot vote on that protocol. The IACUC will review your protocol and place it into one of the three

categories listed below by a majority vote of the quorum present. It will then notify you and the institutional official in writing of the outcome of the review. The three categories to which your protocol can be assigned are:

A. Approved

This means that you can begin work on the project. In specific cases this approval may be made contingent upon the provision by the PI of answers to specific questions to the satisfaction of the Chair of the IACUC. This option is provided to allow missing information to be obtained without the delay of an additional review cycle.

B. Review Pending

This means that the IACUC is requesting additional information (which will be enumerated in the response you receive), and will need to conduct a second review after receipt of the requested information from you. In this case you cannot begin work on the project until written approval is granted by the IACUC following subsequent review. A Review Pending response from the IACUC is usually due to lack of detail in the Narrative section of the protocol. The PI can minimize the risk of the delay associated with a Review Pending response by filling out the Narrative portion carefully, accurately, and completely, and by working closely with the IACUC if uncertain about what types of information are desired by the committee.

C. Not Approved

This means that the IACUC has found problems in the protocol that do not permit its approval. These problems will be identified in writing and you will be given the opportunity to respond in person or in writing. If you receive this response the project cannot be carried out as submitted. If you receive this response, please contact the IACUC and work closely with it to determine if and how it is possible to revise the protocol to make it acceptable. If you decide to revise the protocol, it will have to be submitted for a new review.

9. If you have made a request to the Chair of the IACUC for an expedited review of your protocol, a different procedure for review will be used. For an expedited review, the Chair of the IACUC or IACUC Program Manager will appoint a subcommittee of one or more qualified members of the IACUC to conduct a full review of your protocol. This subcommittee can, by majority vote, approve, require modification of (to secure approval), or request full committee review of your protocol. In addition, the Program Manager will distribute full copies of the protocol to all the members of the Committee. Any member of the IACUC can, within seven days of distribution of this information, request full committee review of the protocol at a regularly scheduled IACUC meeting. If no such request is made within seven days, the Chair of the IACUC will notify you of the outcome of your review based upon the vote of the subcommittee.
10. When an Animal Use Protocol is approved by the IACUC, it is the responsibility of the PI to ensure that 1) all personnel involved in the project are properly trained in the procedures they will carry out, and 2) the project is carried out as described in the approved protocol.

11. It is not uncommon for research designs to change, or new experiments to be added to a research plan, as work progresses. If the research plan for an approved Animal Use Protocol is altered in any substantive way (e.g., use of new drugs, substantive alternations in the number of animals used, a change in the research design or methods involving animals, etc.), you must notify the IACUC in writing of the modification. This should be done in a memo to the Chair of the IACUC which identifies the project by its title and the project number assigned to it by the IACUC at the time of its initial review, and describes the changes in detail comparable to that used in the original narrative portion of the protocol. The IACUC will issue a written response, with the same three possible outcomes as listed in Item 8 for review of a full protocol. In cases where time is of the essence (e.g., the experiment is in progress and changes must be made immediately or data will be lost), you may contact the Chair of the IACUC (or any other member of the IACUC if the Chair cannot be contacted) and ask for approval for minor modifications.

If the Investigator wishes to modify a protocol and the modification is minor such as to extend the study period (as long as it doesn't exceed the 3-year maximum), increase the number of animals to be used (if <10% of the total number of approved animals), minor change in an approved procedure, etc., the Chair will review and approve such modifications. The Investigator must submit a written request for the modification (e-mail requests are acceptable) to the Chair. All correspondence is maintained in the protocol file. The Committee is informed via the Agenda for the next meeting. If the Chair decides that the requested modification cannot be considered minor or for some other reason decides that the request needs full IACUC review, a copy of the Investigator's request will be sent to each Committee member and included on the Agenda for the next scheduled meeting. It will be reviewed using criteria that applied to review of a protocol.

12. In accordance with PHS policy, the maximum duration for which the IACUC can approve an Animal Use Protocol is three years from the time it is approved by the IACUC. If you have an ongoing project that will last more than three years, PHS Policy requires that continuing review of an approved project be conducted by the IACUC every three years, even if the description of the project has not changed. This Institution's IACUC requires that a new protocol be submitted at the end of the 3-year period. If you are submitting an extramural grant proposal that extends for longer than three years and the granting agency requires prior approval by the IACUC, you should submit an Animal Use Protocol for review that covers the entire research plan of the grant. If the IACUC approves the protocol, the initial approval will be for three years. As the end of the three year approval period approaches, you should resubmit the protocol (or a revision of it if your research plan has changed) for approval for the remainder of the grant period. Finally, if you have an Animal Use Protocol that has been approved by the IACUC for a period of less than three years, you can request an extension of that protocol up to the three-year limit by submitting a memo containing your request to the IACUC. Minor alterations in the protocol may be noted in the memo. If any substantive alterations of the protocol are needed, a new Animal Use Protocol should be

submitted. If you do not apply for and receive an extension of an Animal Use Protocol, all work on that protocol must stop by the expiration date.

13. The annual report filed by the University with APHIS mandates annual review of the current status of all active Animal Use Protocols. For this reason if you have an active protocol the IACUC will send you once a year a brief check-list on which to indicate the current status of your project and whether any changes have been made in your protocol. Completion of the check-list will be a very simple process. This checklist must be returned to the IACUC in order for approval of the protocol to continue.

**Animal Use Protocol**  
**University of Arkansas, Fayetteville**  
**Coversheet**

Submit a single paper copy of your completed protocol to **Carol Rodlun**, ANSC A - 42

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IACUC use only:

Protocol number:	Category(s) of animal use:
Date Received:	___ Biomedical
Approval Date:	___ Agricultural
Start Date:	___ Field
End Date:	

---

Project Title:

Project length (3 years maximum):

Start date: \_\_\_\_\_ End date: \_\_\_\_\_

Principal Investigator

Name:	Telephone:
Department/Division:	Fax:
Campus Mail Address:	E-mail:

Individual(s) responsible for animal care

Name:  
Office address:  
Home address:  
Home phone:

Individual(s) responsible for euthanasia

Name:  
Office address:  
Office phone:  
Home address:  
Home phone:

Animals used

Species:  
Common name:  
Approximate number to be used (by species; not a combined number):  
Supplier (all purchases must be from a licensed supplier)  
Name:  
Address:

Locations (building and room)

Animal housing:

Surgical facility:  
Data collection:

**Animal Use Protocol  
University of Arkansas, Fayetteville  
Checklist**

Title of Project: \_\_\_\_\_

Principal Investigator: \_\_\_\_\_

Type of Project:

1.  Teaching  Research
2.  New
3. Category of research and teaching for which this protocol was written:  
 Biomedical  Agricultural  Field

Funding Source (check all that apply):

- NIH  NSF  USDA  private industry  U of A  
 State of Arkansas  other (identify): \_\_\_\_\_

Level of pain or stress (see attachment at end of this form):

- Level 1  Level 2  Level 3  Level 4

Surgical Procedures:

- none  
 non-survival surgery (euthanasia will be administered before recovery from anesthesia)  
 survival surgery (animal will be allowed to recover from anesthesia)  
 multiple survival surgeries (requires explicit justification in Narrative)

Non-Surgical Procedures:

If any of the methods/techniques listed below will be used, check the appropriate space and provide the requested details in Section 2C of the Narrative (Non-Surgical Procedures):

- Non-surgical invasive procedures (blood collection, catheterization, intubation, etc.). Provide appropriate details (volume, site, frequency, etc.)  
 Exposure of a living animal to a hazardous, toxic, and/or radioactive substance. Provide substance name, route of administration, dose, volume, frequency.  
 Exposure of a living animal to an infectious agent. Provide name of agent, means of exposure, and amount and frequency of exposure. Specify in Section 2E of the Narrative the criterion you will use to determine if euthanasia is necessary to relieve suffering.

Non-Surgical Procedures (continued):

- \_\_\_ Immunization protocol. Provide name of adjuvant(s) used; injection site; volume per site; frequency of injection; method, frequency, and volume of blood withdrawn (including anesthetic, if used). **Note: this does NOT apply to standard prophylactic vaccinations.**
- \_\_\_ Prolonged restraint. Provide method, duration, frequency, procedure by which animal is adapted to restraint device.
- \_\_\_ Food/water deprivation. Provide duration, frequency, extent (total/partial), methods used to assess and monitor distress. **Note: removal of food and/or water for 24 hours in preparation for surgery or some other procedure is NOT considered to be “Food/water deprivation”.**
- \_\_\_ Abnormal environment. Provide information on departure from normal conditions (temperature, humidity, light, duration, etc.).
- \_\_\_ Aversive stimuli. Provide type and intensity of stimulus, duration, justification for use.
- \_\_\_ Hybridoma protocol. Provide priming agent, cells injected, schedule for collection of ascites, number of abdominal taps, size of needle used. **Important: Provide justification for use of the *in vivo* mouse ascites method versus the various *in vitro* methods currently available , providing adequate documentation.**
- \_\_\_ Use of neuromuscular blocking agents (muscle paralytics) during surgery. Provide a rationale for their use and explain how you will determine that adequate anesthesia is maintained.
- \_\_\_ Use of death (without euthanasia) as an endpoint of the study. Provide justification why an earlier endpoint is not acceptable.

Method of Euthanasia (must comply with the most recent report of the AVMA panel on euthanasia; provide details in Section 2E of Narrative):

- \_\_\_ none needed
- \_\_\_ overdose of anesthetic
- \_\_\_ inhalation of carbon dioxide
- \_\_\_ physical means under general anesthesia
- \_\_\_ physical means without anesthesia (USDA procedures permit use of captive bolt pistol on large farm animals; otherwise this method can be used only when scientifically justified and requires specific written justification)
- \_\_\_ other (identify here and describe in Narrative):

Disposal of remains:

- \_\_\_ Incineration at University Farm
- \_\_\_ Other (describe in Narrative)

**Animal Use Protocol**  
**University of Arkansas, Fayetteville**  
**Narrative**

(Note: only items in **boldface** need be reproduced on your protocol; the remaining text is provided to help you prepare your answers)

**1. ABSTRACT** (approximately 100-300 words)

Please provide, in lay language, a concise but specific statement of the scientific objective for the proposed research, the rationale behind this objective, the species of animal to be used, and an overview of the procedures to be followed. This statement should stand alone and be comprehensible to a non-scientist.

**2. METHODS**

Using the headings listed below, describe the methods to be used in your project. The level of detail for procedures involving animals should be comparable to that in the Methods section of a journal article (i.e., sufficient to enable another researcher competent in your field to replicate your study).

**A. Housing**

Describe how the animals will be housed, including cage size and number per cage where applicable.

**B. Experimental design**

Provide an overview of the experimental design, including a schedule or timetable of the treatments animals will be exposed to and their duration.

**C. Non-surgical procedures involving animals**

Be particularly detailed regarding any procedures that are invasive, involve stress, or cause tissue damage.

**D. Surgical procedures**

(Note: Written records of surgery and anesthesia must be kept for each animal.

Animals must be observed daily following surgery and observations must be recorded from the time surgery is completed until incisions are healed).

**1. Surgeon(s)** (list qualifications for the procedures to be carried out)

**2. Procedure** (must use aseptic techniques)

**3. Medication**

For all medications, specify the agent, the route of administration (e.g., i.m.), the dose (mg/kg), and, when appropriate, the frequency of administration.

**A. Pre-operative medication and preparation**

**B. Anesthesia and other medication during surgery**

**C. Post-operative medication and observation**

**E. Euthanasia**

Identify the method of euthanasia to be used. If your protocol may cause animals to become seriously ill, specify the criterion you will use to determine if and when euthanasia will be used to relieve suffering. If euthanasia will not be used, indicate what will happen to the animals at the end of the study.

**3. QUALIFICATIONS OF INDIVIDUALS PERFORMING WORK WITH ANIMALS**

Please list all individuals who will be carrying out procedures involving animals during this project. Please indicate who will be performing each procedure and their qualifications for that procedure. If individuals are to be trained in a procedure during this project, please indicate who will provide the training and supervision and their qualifications.

- A. Principal Investigator** (a current vita should be on file with the IACUC)
- B. Students** (attach resume or provide a brief description of qualifications)
- C. Lab Technicians** (attach resume or provide a brief description of qualifications)
- D. Individuals Providing Training or Supervision** (attach resume or provide a brief description of qualifications)

**4. STATEMENT OF COMPLIANCE:**

**As the individual responsible for this research or teaching project,**

**I confirm that the information contained herein is accurate and, to the best of my knowledge, conforms with all applicable University, PHS, and USDA policies on the use of animals in research and teaching.**

**I confirm that all individuals who will be involved with the animals used in this project have been instructed in the humane care, handling, and use of animals, and that I have reviewed their qualifications.**

**I agree not to proceed with any portion of this project or purchase animals until I receive written approval from the University of Arkansas Institutional Animal Care and Use Committee (IACUC).**

**I agree that no substantive change will be made in the procedures contained in this proposal without prior written notification to and approval by the IACUC.**

**I agree to allow inspection of my research facilities by members of the IACUC and the Animal Welfare Veterinarian and to comply promptly if informed of any violations of the University of Arkansas, Fayetteville's Policy on Animal Care and Use.**

**I understand that failure to comply with the University of Arkansas, Fayetteville's Policy on Animal Care and Use will jeopardize the University's Animal Welfare Assurance on file with the PHS (and with it all federal funding for the University), and may ultimately lead to revocation of my privileges to conduct animal research at the University of Arkansas.**

---

Signature of Principal Investigator

---

Date

**Animal Use Protocol**  
**University of Arkansas, Fayetteville**  
**Assurance Statements for Biomedical Research and Teaching**

**DO NOT COMPLETE THIS SECTION IF PROTOCOL IS SPECIFIED AS**  
**AGRICULTURAL or FIELD RESEARCH**

(Note: only items in **boldface** need be reproduced on your protocol; the remaining text is provided to identify the source of the requirements)

**The regulations for the Animal Welfare Act, the United States Department of Agriculture, and the Public Health Service require that in protocols for biomedical research and teaching involving animals the following concerns be specifically addressed in writing by the Principal Investigator.** Items in brackets [] identify the source of the requirement (AWA = Animal Welfare Act regulations; NIH = NIH Guide for Care and Use of Laboratory Animals, 1996 edition).

- A. Animals should not be used if other methods exist that would provide substantially the same information. Indicate why the use of live animals is required in this research.** [AWA 2.31 (e) (2); NIH p. 8]
- B. Justify your choice of species by listing some of the important characteristics of the species that make it suitable for use in the proposed research. Cost alone is not sufficient rationale.** [AWA 2.31 (e) (2); NIH p. 8]
- C. The number of animals used should be the minimum number that can be expected to provide valid results. Describe how the number of animals to be used was determined.** [AWA 2.31 (e) (2); NIH p. 8]
- D. The principal investigator should not unnecessarily duplicate previous experiments, and must consider less invasive alternatives to procedures that may cause more than momentary or slight pain or distress to animals (i.e., Level 3 or higher). Provide a statement that a literature review has been carried out demonstrating that this research does not unnecessarily duplicate previous experiments, and that appropriate alternative research methods are not available for any proposed procedures that are Level 3 or higher. The database used must be identified (check below).** [AWA 2.31 (d) (1) (I, ii, and iii); NIH p. 8]

**Database:**

- Medline**    **Agricola**    **Index Medicus**    **Biol. Abstracts**  
 **Animal Welfare Information Center (National Agricultural Library)**  
 **Other (please specify):**

**Signature:**

\_\_\_\_\_  
**Principal Investigator**

\_\_\_\_\_  
**Date**

## Grading of Pain and Stress in Research Using Animals

<u>Level</u>	<u>Examples and Comments</u>
<u>Level 1</u> Experiments on vertebrate animals that are expected to produce little or no discomfort.	Simple procedures such as injections and blood sampling; observational field behavior; physical examinations; experiments on anesthetized animals that do not regain consciousness; food/water deprivation for short periods and methods of euthanasia that induce rapid unconsciousness.
<u>Level 2</u> Experiments that involve some minor stress or short-duration pain to vertebrate animals.	With anesthesia, "cut downs" or implantation of catheters; behavioral experiments on conscious animals that involve restraint; immunization employing Freund's adjuvant; noxious stimuli from which escape is possible; surgical procedures under anesthesia that may result in postsurgical discomfort.
<u>Level 3</u> Experiments that involve significant unavoidable stress or pain to vertebrate animals.	Deliberate induction of behavioral stress; major surgical procedures under anesthesia that result in significant postoperative discomfort or an anatomic or physiologic deficit that will result in pain or distress; noxious stimuli from which escape is impossible; prolonged periods of physical restraint; procedures that produce pain in which anesthetics are not used (toxicity testing, radiation sickness, certain injections, and stress and shock research, experimental infection producing systemic disease or death). Level 3 mandates responsibility on the part of the investigator to explore alternative designs.
<u>Level 4</u> Procedures that involve inflicting severe pain on unanesthetized, conscious animals.	Use of muscle relaxants or paralytic drugs without the use of anesthetics; surgery, severe burn or trauma infliction on unanesthetized animals; attempts to induce psychotic-like behavior or severe stress or terminal stress. Many of these procedures are specifically prohibited and therefore may result in withdrawal of federal funds and/or institutional USDA registration.

Note: The preceding levels correspond to the following animal use categories on the APHIS annual report form: Level 1 = Category C or D; Level 2 = Category D; Levels 3 and 4 = Category E.

ATTACHMENT #5 (Annual Review Form)

**MEMORANDUM**

DATE:

TO:

FROM: Carol A. Rodlun, Program Manager  
Institutional Animal Care and Use Committee (IACUC)  
AFLS A-42

SUBJECT: **ANNUAL REVIEW OF ANIMAL USE PROTOCOL** [Protocol #]  
[Protocol Title]

USDA/APHIS policy requires that the IACUC conduct Annual Reviews of the current status of active animal research protocols. The IACUC should be notified of changes in species, animal numbers, procedures, surgery, and methods of anesthesia and euthanasia by completing this form and submitting justification memos as required below. Please answer all items that apply. **You must respond to items 1) and 2)** . Thank you for your prompt attention to this matter.

**COMPLETION AND RETURN OF THIS FORM IS REQUIRED FOR CONTINUATION OF YOUR RESEARCH PROJECT.**

1). **Current status of study:**

- Study is currently underway
- Initiation of the study is pending
- Study has been completed, please terminate protocol
- Study will not be conducted, please terminate protocol

2). **Have there been changes in the protocol since the last review?**

- Yes       No

If **Yes**, attach an explanation and justification memo for any of the following. Please indicate all **CHANGES** that apply.

- a.  Animal species
- b.  Experimental procedures
- c.  Euthanasia method/agent
- d.  Personnel
- e.  Study location

3). **Change in Title or Principal Investigator** (List changes below)

\*\*\*\*\*

Signature of PI \_\_\_\_\_

Date

Approved: \_\_\_\_\_  
IACUC Committee Chair

Date

ATTACHMENT #6

## RESEARCH MISCONDUCT POLICIES AND PROCEDURES

(Campus Council, May 4, 1989)

The University of Arkansas, Fayetteville, will pursue allegations of research misconduct. This pursuit will involve an inquiry of the allegation; an investigation if the inquiry indicates one is warranted; and imposition of sanctions if justified.

### I. Definition of Terms

*Research misconduct* means (1) fabrication, falsification, plagiarism, deception, or other practices which seriously deviate from those commonly accepted within the research community for proposing, conducting, or reporting the results of research; (2) material failure to comply with federal, state, or local requirements, for protection of researchers, human subjects, the public, or laboratory animals, or other requirements which relate to the conduct of research; or (3) failure to meet other material legal requirement governing research. The term research misconduct as used in this document does include such improper activities as plagiarism of original literature and unauthorized copying of original artwork.

*Inquiry* means information gathering and initial fact-finding to determine whether an allegation or an apparent instance of research misconduct warrants an investigation.

*Investigation* means the formal examination and evaluation of all relevant facts to determine if research misconduct has occurred.

*The appropriate office of research administration* for the University of Arkansas, Fayetteville, is either the Office of Research and Sponsored Programs or the University of Arkansas Agricultural Experiment Station.

*The date of initiation of the investigation* is the day the Vice Chancellor for Academic Affairs is notified by the Chair of the Research Council that an investigation is necessary.

## PROCESS FOR HANDLING RESEARCH MISCONDUCT

### II. The Inquiry

- A. An inquiry is not a formal hearing; it is designed to separate allegations deserving further investigation from frivolous, unjustified, or clearly mistaken allegations. The inquiry must result in either dismissal of the allegation or a call for an investigation. A suspected criminal act will result in the suspension of the inquiry until the appropriate law enforcement agency allows it to continue.

- B. Allegations of research misconduct will be submitted to the Vice Chancellor for Academic Affairs and should be as specific and as detailed as conditions permit. These allegations will normally be submitted in writing and signed by the complainant(s). When the complainant(s) elect(s) to not submit a signed document, the Vice Chancellor for Academic Affairs shall exercise discretion as to whether the information presented warrants an inquiry. Whenever possible, the Vice Chancellor shall counsel confidentially with the complainant(s).
- C. The Vice Chancellor for Academic Affairs will immediately charge the Chair of the Research Council with conducting an inquiry into the allegation of research misconduct. The inquiry will then be conducted by the Research Council. All members of the Research Council must disclose potential conflicts of interest to the Council which will determine if conflicts exist and excuse member(s) from the inquiry as appropriate. In the event the Chair of the Research Council has possible conflicts of interest, the Research Council will elect a chair of the inquiry from its membership. That person will perform the same duties detailed for the Chair of the Research Council.
- D. The inquiry must be initiated immediately upon receipt of an allegation of research misconduct by the Chair of the Research Council. The inquiry should be completed within 60 calendar days of the date the chair received the allegation. If circumstances clearly warrant a period of longer than 60 calendar days for the inquiry, the reasons for the extended time period shall be submitted in writing to the Vice Chancellor for Academic Affairs.
- E. If criminal conduct is suspected, the appropriate authorities will be notified and the inquiry will be suspended until those authorities notify the Research Council that it is appropriate to reconvene the inquiry.
- F. A written record must be kept of the inquiry including, if necessary, the reasons for an extended inquiry period. The safety and security of the record will be assured. The Chair of the Research Council will assume responsibility for the written record and other materials acquired during the progress of the inquiry. The materials and record will be kept in the Office of Research and Sponsored Programs. Members of the Research Council wishing to view those materials and/or the written record at times other than when the Council is in session (for purposes of conducting the inquiry) must go to the Office of Research and Sponsored Programs. Only the Chair of the Research Council or those designated by the Chair may remove the record or materials and then only to bring to the Council for the purpose of conducting the inquiry.
- G. During the inquiry stage, the University of Arkansas, Fayetteville, will protect the confidentiality of all parties involved to the maximum extent possible. Whether a case can be reviewed effectively without the involvement of the complainant(s) or the person(s) alleged to have committed research misconduct depends upon the nature of the allegation and the evidence available. Cases that depend specifically upon the

observations or statements of the complainant(s) may not proceed without the involvement of that individual; other cases that rely on documentary evidence may permit the complainant(s) to remain anonymous. It may be necessary to involve the person(s) alleged to have been involved in research misconduct during the inquiry. In such instances the person(s) must be advised of the allegation of research misconduct.

- H. The complainant(s) and the person(s) alleged to have been involved in research misconduct shall supply information and material as requested by the Research Council.
- I. Both the complainant(s) and the person(s) charged in the allegation may seek legal counsel. Such counsel will not be allowed to be physically present during the inquiry sessions.
- J. The completion of an inquiry is marked by the Research Council's determination of whether or not an investigation is warranted and the preparation of written documentation to summarize the process and conclusion of the inquiry. The Chair of the Research Council will provide a written report of the findings of the inquiry to the Vice Chancellor for Academic Affairs. If an investigation is needed, the Vice Chancellor for Academic Affairs will so notify in writing the complainant(s), the person(s) alleged to have been involved in research misconduct, the appropriate deans and chairs, the appropriate office of research administration, and all other persons who have been informed of the inquiry by the Research Council or University officials. If the allegations have been found to have no substance, the Vice Chancellor for Academic Affairs will immediately notify in writing only those persons informed of the inquiry and move to restore all situations to as close to their original conditions as possible.
- K. If the need for an investigation is determined, any agency sponsoring the research will be immediately notified in writing by the appropriate office of research administration. The funding agency may be informed before the inquiry is complete if (1) the seriousness of alleged misconduct is apparent; (2) immediate health hazards are involved; (3) the funding agency's resources, reputation, or other interests need protecting; (4) federal action may be needed to protect the interests of a subject of the investigation or of others potentially affected; or (5) the community or the public should be informed. If at any point in an inquiry criminal violations become apparent, the funding agency will be notified within 24 hours if at all possible. The appropriate legal authorities will also be notified. The funding agency will be notified if the alleged research misconduct is going to be publicly announced by the University.
- L. During the inquiry, interim administrative action may be taken by the Vice Chancellor for Academic Affairs when justified by the need to protect the health and safety of research subjects, the interests of students and colleagues, or the University. Administrative action may range from slight restrictions of activities, reassignment of activities, or suspension of all research activities of the person(s) alleged to have committed research misconduct.

Interim administrative action will be taken in full awareness of how it might affect the individuals and the ongoing research within the insitution.

### **III. Rights of the Compainant(s) and Persons Alleged to have Committed Research Misconduct**

- A. The proceedings of an inquiry, including the identity of the person(s) alleged to have committed research misconduct, will be held in strict confidence to protect the parties involved. If confidentiality is breached and the inquiry finds the allegation to be unsupported, the Vice Chancellor for Academic Affairs will take reasonable steps to minimize the damage to reputations which may result from inaccurate reports.
- B. If an allegation is found to be unsupported but has been submitted in good faith, no further formal action will be taken other than the notifications required by paragraph II.J above. Allegations that have not been brought in good faith will lead to appropriate disciplinary aciton. Complainants should be aware from the outset that their confidentiality will not be maintained if the Research Council determines that the complaint is maliciously motivated and false. Such complaints will be considered to be research misconduct.
- C. Where a complaint has been brought in good faith even if mistaken, the Univesity will protect the complainant(s) against retaliation. Individuals engaging in acts of retaliation will be disciplined in accordance with the policies of the University of Arkansas, Fayetteville.

### **IV. The Investigation**

- A. The investigation's purpose is to explore further the allegations and determine whether research misconduct has been committed. The investigation will focus on accusations of research misconduct as defined previously and examine the factual materials of each case. The investigation will look carefully at the substance of the charges and examine all relevant evidence.
- B. Once the Research Council has determined an investigation is required, it must be conducted. The person(s) alleged to have committed research misconduct does not have the right to challenge the initiation of the investigation.
- C. The Research Council will determine the composition of the investigative committee and insure that it has the appropriate expertise to evaluate the evidence. It may be possible to utilize an existing committee, the presence of which may be mandated by federal agencies. For example, the Institutional Animal Care and Use Committee may be the appropriate body to investigate an allegation of mistreatment of laboratory animals. Members of the investigative committee may come from within or outside the University of Arkansas, Fayetteville. The Vice Chancellor for Academic Affairs will provide the necessary resources for outside experts when sufficient expertise does not exist at the

University of Arkansas, Fayetteville. The minimum number of committee members will be five. The Research Council will appoint the chair of the investigative committee.

- D. Conflicts of interest must be avoided. Those investigating the allegations will be selected and serve with full awareness of the closeness of their professional or personal affiliation with the complainant(s) and/or the person(s) alleged to have committed research misconduct. Any person appointed to an investigative committee who may have a conflict of interest in a given case must disclose potential conflicts to the Chair of the Research Council in writing within one week. The Research Council will determine if a conflict exists and rescind or continue the appointment as appropriate.
- E. The Vice Chancellor for Academic Affairs and the person(s) alleged to have committed research misconduct will be notified in writing by the Chair of the Research Council as to the composition of the investigative committee.
- F. The person(s) alleged to have committed research misconduct shall have an opportunity to respond to the allegation. Any initial response to the allegation should be received in writing by the Chair of the Research Council within 15 calendar days following the date of the notification letter described in IV.E. The Chair of the Research Council shall immediately forward any response to the chair of the investigative committee.
- G. The investigation will be conducted as expeditiously as possible. In most cases the investigation will be completed within 120 calendar days of its initiation. In certain cases 120 days may be insufficient. In such cases the investigative committee will prepare an interim written report by the 120th calendar day after the initiation of the investigation to report progress to date, including reasons for the extra time required for the completion of the investigation. The chair of the investigative committee will distribute the report to the Vice Chancellor for Academic Affairs, the person(s) alleged to have committed research misconduct, the appropriate office of research administration, and the Chair of the Research Council.
- H. Written records and all other materials pertinent to the investigation will be kept in the Office of Research and Sponsored Programs and will be available only to individual investigative committee members. Only the chair of the investigative committee or his/her designee may remove the records and material.
- I. In the course of an investigation, additional information may emerge which justifies broadening the scope of the investigation beyond the initial allegations. Any such change in scope will be immediately reported in writing by the chair of the investigative committee to the Chair of the Research Council who will notify the Vice Chancellor for Academic Affairs, the complainant(s), the person(s) alleged to have committed research misconduct, and the appropriate office of research administration. The appropriate office of research administration will report significant new developments during the investigation to any sponsor(s) of the research as they occur.

- J. The person(s) alleged to have committed research misconduct must provide information requested by the investigative committee. All involved parties are obligated to cooperate with the investigative committee in providing information relating to the case.
- K. Throughout the investigation, the person(s) alleged to have committed research misconduct may, at the discretion of the investigative committee, be advised of the progress of the investigation and afforded the opportunity to respond and/or provide additional information to the investigative committee.
- L. The person(s) alleged to have committed research misconduct will be allowed to submit written statements from others, to appear before the investigative committee and make an oral statement, and answer questions. In any appearance before the investigative committee, the person(s) alleged to have committed research misconduct may be accompanied by one person, who may be an attorney, to advise him/her. The adviser shall not address the investigative committee, speak on behalf of the person, or otherwise participate actively in the investigation. The person(s) alleged to have committed research misconduct may not be present during testimony of other witnesses or during committee deliberations, nor may he/she have access to committee records.
- M. In the event criminal actions are discovered during the investigation, the proper authorities will be notified and the investigation will be suspended until those notified authorities approve its resumption.
- N. During the investigation, interim administrative action may be taken by the Vice Chancellor for Academic Affairs when justified by the need to protect the health and safety of research subjects, the interests of students and colleagues, or the University. Administrative action may range from slight restrictions of activities, reassignment of activities, or suspension of all research activities of the person(s) alleged to have committed research misconduct. Interim administrative action will be taken in full awareness of how it might affect the individuals and the ongoing research within the institution.
- O. The investigation into allegations of research misconduct may have any number of outcomes, including but not limited to a determination that:
  - 1. no research misconduct or serious research error was committed;
  - 2. no research misconduct was committed, but serious research errors were discovered in the course of the investigation; or
  - 3. research misconduct was committed.
- P. The investigative committee will provide a draft report to the Chair of the Research Council who will provide copies to the person(s) alleged to have committed research misconduct, the complainant(s), and the Vice Chancellor for Academic Affairs for their comment prior to preparation of the final written report. This report will contain the tentative findings of the investigative committee with its rationale. The investigative committee will allow at least 15 calendar days from the date the report is mailed to the

Chair of the Research Council for input from any of the parties receiving the draft report before preparing the final report. Copies of the final report will be distributed by the Chair of the Research Council to the person(s) alleged to have committed research misconduct, the complainant(s), the Vice Chancellor for Academic Affairs, and the appropriate office of research administration.

## **V. Procedures Once the Investigation is Complete**

- A. The Research Council will conduct a substantive review of the findings and rationale of the investigative committee within 15 calendar days from the date of the final report of the committee. The Research Council may accept or modify the findings of the investigative committee and shall recommend corrective or disciplinary action, if appropriate. The Chair of the Research Council will report in writing the action of the Research Council to the Vice Chancellor for Academic Affairs, the chair of the investigative committee, the complainant(s), those alleged to have committed research misconduct, the appropriate office for research administration, and others notified of the investigation.
- B. **No Finding of Research Misconduct:** When the investigation finds no support for allegations of research misconduct and the Research Council concurs, the University of Arkansas, Fayetteville, will retain the findings of the investigation in a confidential and secure file in the Office of Research and Sponsored Programs. The Chair of the Research Council will notify in writing all persons informed of the investigation that the allegation lacked substance. The Vice Chancellor for Academic Affairs will take reasonable steps to repair the reputations of those alleged to have committed research misconduct.

If the allegations of research misconduct are found to be maliciously motivated, appropriate disciplinary actions will be taken against those responsible. If the allegations, however incorrect, are found to have been made in good faith, no disciplinary measures will be taken against the complainant(s), and efforts will be made to prevent retaliatory actions. The Vice Chancellor for Academic Affairs will be responsible for these efforts.

- C. **Serious Research Error is Found:** When serious research error has been found, the University of Arkansas, Fayetteville, will consider means of correcting the research record. When appropriate, this will involve written notification by the Chair of the Research Council to the editors of appropriate journals or other documents in which the errors were reported.

Sanctions may be imposed on those found to have committed serious research error. The Chair of the Research Council will notify all persons informed of the investigation that serious research error has occurred.

- D. **Finding of Research Misconduct:** Sanctions will be imposed on those found to have committed research misconduct.

## **VI. Sanctions**

- A. The Vice Chancellor for Academic Affairs will review the corrective or disciplinary action recommended by the Research Council. The Vice Chancellor may implement the action as recommended or modify it as appropriate.
- B. Institutional disciplinary actions include but are not limited to:
  - 1. special monitoring of future work,
  - 2. letter of reprimand,
  - 3. removal from a particular project,
  - 4. probation,
  - 5. suspension,
  - 6. salary reduction,
  - 7. rank reduction, and
  - 8. termination of employment.
- C. The Vice Chancellor for Academic Affairs will report in writing the sanctions imposed to the person(s) found to have committed serious research error or misconduct, the complainant(s), the Chair of the Research Council, the appropriate deans and chairs, and the appropriate office of research administration which will notify the research sponsor(s).

## **VII. Brief Final Report**

- A. The Chair of the Research Council will prepare a brief final report which summarizes the findings of the investigative committee, the action of the Research Council, the sanctions imposed by the Vice Chancellor for Academic Affairs, and any additional related actions by the involved parties. When no finding of serious research error or misconduct is found, the Chair of the Research Council will distribute the final report only to those informed of the investigation. When serious error or misconduct has been found, the Chair of the Research Council will distribute the final report to those informed of the investigation and to appropriate individuals and agencies in the following list. The list is illustrative but not exhaustive of those who should receive the brief final report:
  - 1. sponsoring agencies, funding sources;
  - 2. co-authors, co-investigators, collaborators;
  - 3. editors of journals in which inappropriate research was published;
  - 4. state professional licensing boards;
  - 5. editors of journals or other publications, other institutions, sponsoring agencies, and funding sources with which the individual has been affiliated;
  - 6. professional societies;
  - 7. legal authorities if appropriate; and
  - 8. the person(s) who committed the research error misconduct.

The original copy of the final report will be stored in the Office of Research and Sponsored Programs with the other documents pertaining to the investigation.

- VII.** The Vice Chancellor for Academic Affairs will issue a press release following a finding that serious research error or misconduct has occurred and sanctions have been imposed.
  
- IX.** The University of Arkansas, Fayetteville, recognizes that sponsoring agencies can conduct their own inquiries and investigations and impose their own sanctions.

ATTACHMENT #7 [most recent semi-annual report on program and site evaluation]