

**INSTRUCTIONS FOR COMPLETING
THE FLORIDA STATE UNIVERSITY ANIMAL CARE AND USE COMMITTEE
ANIMAL USE DESCRIPTION (AUD)
FOR PROPOSED VERTEBRATE ANIMAL USE**

The value of animal research, both basic and applied, is widely acknowledged and has been explicitly recognized by Congress in the wording of the Animal Welfare Act. In its pursuit of excellence, the Florida State University is committed to providing a high quality animal care and use program that meets or exceeds all Federal regulations and guidelines. As a key element of the animal care and use program, the FSU Animal Care and Use Committee (ACUC) acts as an agent of the University to help investigators meet the federal, state and university requirements for conducting research with vertebrate animals. One of the requirements is that all uses of vertebrate animals in research and instruction, whether externally funded, internally funded, or unfunded, be approved by the ACUC before the activity is undertaken. The ACUC is also required to consider specific aspects of the proposed research when the activity is governed by the Animal Welfare Act or subject to the PHS Policy on Humane Care and Use of Animals. Appendix 1 provides more detail on USDA regulations regarding the specific responsibilities of the ACUC. Additional information on PHS Policy is available from the FSU Department of Laboratory Animal Resources (LAR).

REVIEW PROCESS: In order to use vertebrate animals in research or teaching at FSU an Animal Use Description form (AUD) must be submitted and approved by the ACUC. The AUD protocol will be reviewed by LAR's Director, attending veterinarian and ACUC Secretary prior to submission to the ACUC. Full committee approval will take place at the monthly ACUC meeting. Summary of ACUC Review Procedures is provided in Appendix 2.

ANNUAL (covered species) / TRI-ANNUAL REVIEW (non-covered species): Depending upon the species used, the AUD protocol will be due for review either one or three years after approval. At this time, the form may need to be updated. Reminders will be sent two months before your approval expires.

SIGNIFICANT CHANGES: Changes in animal use may require approval by the ACUC. To determine if a change requires ACUC approval (such as an increase in the number of animals used), review the "Guidelines for Reporting Significant Changes to Proposals for Vertebrate Animal Use" provided as Appendix 3. Changes can be made by submitting a "Significant Change" form, as described in Appendix 2. Any significant modification to the AUD must be reviewed by the ACUC before that change is implemented.

ANIMAL ORDERS: All vertebrate animal purchases must be made through the FSU Department of Laboratory Animal Resources (LAR). Purchase requests may only be initiated by individuals listed on the approved AUD protocol. AUD protocol numbers must be used when ordering animals through LAR.

FREEDOM OF INFORMATION ACT: Once the AUD protocol is submitted to the committee, it is considered to be available to the public under the Freedom of Information Act.

TRANSMITTAL PAGE: This page is intended for transmittal purposes only and will not be part of the official AUD protocol and will not be made available under the Freedom of Information Act.

Indicate if this is a new AUD protocol, a renewal, or a re-submittal. If this is a renewal or re-submittal, cite the original AUD protocol number. Keep in mind that for renewals and resubmittals, all previous paperwork is also submitted to the ACUC for review and remains a part of the official file of the protocol. If there are appreciable changes, it is best to submit a new AUD protocol form as it eliminates confusion and questions regarding previously approved protocols.

SECTION 1 - ANIMAL USAGE

- a. Provide the proposed length of time animal use will be required.
- b. Indicate the **common and scientific** name for each species to be used for the project.
Provide the maximum number of animals by species to be used for the entire project.
Estimate the number of animals used in each of four USDA categories (explained on page 1 of the Animal Use Description).

The Animal Welfare Act regulations require each research facility to submit an annual report every November 15 with the numbers of animals used and which USDA category each animal falls under. While it is recognized that it will often be impossible to provide the precise number of animals which will be used in each category before the study begins, an **estimate** must be provided.

Category B indicates no use of animals other than breeding, conditioning, or retaining for future use, but not yet used. The Category B estimate total for most projects (other than breeding) will be 0 since it is assumed no animal will be held with no use for the entire project.

Category C indicates the use of animal involves no pain or distress.

In order for a protocol to be listed in Category D, appropriate anesthetics/analgesics must be used if the animal will experience more than momentary slight pain. Momentary slight pain is defined as pain no greater than the level and duration of pain attending a routine injection or procedure.

If Category E is indicated, the protocol must provide reasons for withholding anesthetics/analgesics. All protocols involving Category E procedures must be accompanied by the ACUC form "Explanation for Category E Listing" as provided in Appendix 4.

SECTION 2 - USE OF HAZARDOUS AGENTS

If radioactive isotopes, hazardous materials, or etiologic agents are **used in animals**, call Environmental Health and Safety, 644-5374 or 644-8916, for appropriate forms. Include completed forms with the Animal Use Description (AUD). Laboratory Animal Resources and Environmental Health and Safety will review the use of these substances in animals and determine what and/or if safety precautions are needed to assure the safety of all animals and personnel to the FSU Animal Care and Use Committee.

SECTION 3 - POTENTIAL PAIN OR DISTRESS TO ANIMALS

Check appropriate boxes and provide information where indicated.

SECTION 4 - METHOD OF EUTHANASIA

All methods of euthanasia must follow the recommendations of the 1993 AVMA Panel on Euthanasia. This document is distributed as part of the FSU Basic Training Course materials for research investigators and is available from the LAR office.

SECTION 5 - HOUSING REQUIREMENTS

Approval by the ACUC of the Animal Use Description does not assure that housing is available to perform the project. Caging should be described and arrangements must be made with LAR before beginning the project.

SECTION 6 - PURPOSE OF RESEARCH

This section is maintained on file in the LAR administrative office, at the Office of Research, and in each of the departmental chairs offices and is used for answering public inquiries concerning your research. The statement should stand alone and be easily understood by the lay reader.

SECTION 7 - DESCRIPTION OF ANIMAL USE

You should describe animal use procedures using language understandable to the lay reader. All abbreviations and terms not part of common usage should be clearly defined.

This section is intended to give an overview of the study, and clarify how the experimental procedures will accomplish the study objectives. Details of individual animal procedures must be provided.

Procedural Details:

Adequate information should be provided to describe what is being done. For example, if injections are being given, the substance, dose, volume, and route should be provided; if blood is being collected, give the volume, frequency, withdrawal sites; if radiation is used, give dose/activity and schedule.

Rationale / Number of animals used / Appropriateness:

Information as to why it is necessary to use animals should be provided. The use of animals, e.g., why cell culture or computer simulations cannot be used instead of animals, should be provided.

PHS policy specifies that studies use the minimum number of animals required to obtain valid results. Information addressing this issue should be provided.

The appropriateness of the species of animals to be used, e.g., why a lower order mammal, invertebrate, etc., cannot be used and the appropriateness of the species being used should be addressed in this section. As specified by the Animal Welfare Act the ACUC must "ensure that the type and number of animals proposed are appropriate and necessary" to accomplish the goals of the project.

Food Restriction:

The use of food restriction should be fully described in this section and justified in Section 8.

Degree of restriction (% baseline body weight, complete, etc.), period of time restricted, method and frequency of monitoring should be described.

Many investigators feel a weight loss of greater than 15%-20% is cause for concern and that animals should be monitored to determine if the animal's weight drops below this level.

Sample Statement: *Animals are weighed three times per week, and food portions take into consideration current weight with respect to target weight. Target weight is defined as that weight at which the animal is healthy and active, but has little excess fat. If an animal consistently falls 10% below target weight, more food is provided, regardless of behavioral performance in the test chamber, until target weight is reached. Water is always available.*

Restraint:

Restraint type (chair, sling, harness, etc.), length of time restrained, any conditioning/training required should be detailed (short-term restraint for routine minimally painful procedures such as drawing blood samples does not require detailed explanation). To minimize potential suffering or stress, the period of restraint should be the minimum required to accomplish the research objectives. Animals to be placed in restraint equipment should be conditioned to such equipment prior to the institution of the use of equipment for studies. Animals that are physically restrained must be carefully observed throughout the period of restraint.

Descriptions of restraint would include reference to the need for restraint, the type of restraint, duration of restraint, and monitoring procedures.

Pre- and Postoperative Care:

Refer to ACUC Pre- and Postoperative Guidelines distributed as part of the FSU Basic Training Course materials for research investigators for more information. The Guidelines are available from the LAR office.

A statement under this section that the ACUC Pre- and Postoperative Guidelines will be followed is generally sufficient to address this issue.

Anesthesia, Analgesia, Tranquilization:

Type and dose of anesthetic, analgesic, and tranquilizer or sedative must be appropriate for both the species being used and the type pain or distress being prevented/relieved. Doses and routes of administration should be clearly appropriate and effective, i.e., commonly accepted or published doses, or experience with that agent and dose described which demonstrates its effectiveness. The schedule or indications for administration should be provided, e.g., every 12 hours, as needed, etc. If agents are to be given "as needed", a brief description of the indications for its administration should be provided, e.g., "at the first indication of discomfort as evidence by lethargy, anorexia, hunched posture, eye squinting, or vocalization."

Surgery:

Survival surgery is defined as a surgical procedure from which the animal is allowed to recover from anesthesia. Non-survival surgery is a surgical procedure in which the animal is euthanized prior to recovery from anesthesia. A major operative procedure is one that penetrates and exposes a body cavity, or any procedure which produces permanent impairment of physical or physiological function. General issues that must be addressed if the animal use includes surgery are:

Identify the surgical procedure(s) to be performed.

A complete description, including the use of aseptic technique, and the dose and route of administration of anesthetic and a brief description of the parameters used to monitor the level of anesthesia during surgery, e.g., vital signs, muscle tone, etc., should be included.

If animals are to be paralyzed with chemical agents under anesthesia, anesthetic monitoring is critical. Please include parameters used to determine when more anesthetic is to be given. References indicating that monitoring procedures are appropriate would be helpful.

Survival surgery on rodents must be performed using aseptic technique in a suitably prepared area. Aseptic technique and dedicated surgical facilities are required for survival surgery proposed in rabbits and other higher species such as cats, dogs, and non-human primates. Assurance that aseptic survival surgery will be provided is required under this section.

In the description of recovery/post surgical care, include any needed supportive therapy (external heat pads, IV fluid support, etc.); any surgical site or catheter care procedures; specialized diets, antibiotics, analgesics, etc.; and the approximate length of time the animal will be maintained between surgery and the end of its use in the project. Also include observations necessary to evaluate animal's recovery and continued good health, e.g., daily observation of surgical site for proper healing, proper appetite, weight maintenance, etc. Method(s) of handling potential postoperative complications should be briefly described, e.g., veterinary consultation and assistance will be obtained.

Survival Surgery not Incorporating Aseptic Procedures:

If survival surgery will not incorporate aseptic procedures, the procedures and reasoning should be fully described in this section and justified under Section 8.

Multiple Operative Procedures:

The Animal Welfare Act specifies, "No animal will be used in more than one major operative procedure from which it is allowed to recover, unless...justified for scientific reasons by the principle investigator, in writing;...". Economic cost of additional animals is not an acceptable justification for performing multiple major survival surgeries on the same animal. Many "surgically modified" animals (e.g., adrenalectomized, splenectomized, etc.), have received a major survival surgery prior to being placed on the study, and cannot receive an additional major survival surgery during the study unless justified as scientifically necessary to accomplish the goals of the study. All multiple operative procedures must be fully described under this section and justified under Section 8.

Pain or Distress without Anesthetic or Analgesic:

If procedures will cause pain or distress that would normally be relieved with analgesics or anesthetics, but these compounds cannot be used because of interference with the proposed research, complete procedural details should be provided here and justification should be provided in Section 8. In addition, the form Explanation for Category E, which is appendix 4 of this document must be completed and submitted with the ACUC Protocol.

Electric Shock:

The use of electric shock should be fully described under this section and justified in Section 8. A sample statement under this section would be as follows.

Sample Statement: *A conditioned avoidance procedure will be used. Whenever the warning stimulus is presented, a weak but instantly escapable and entirely avoidable shock is delivered a fixed time later. The minimum shock is carefully titrated for each individual animal. The shock is usually less than 0.5 milliamp and electronically limited to less than 1 milliamp. The animal avoids the shock by breaking contact with the food trough. After a few presentations of this warning signal-shock combination, the animal breaks contact with the food trough whenever the warning stimulus is presented. This break in eating is used as evidence that the change from safe signal to warning signal has been perceived and that therefore, the two signals are discriminable. By systematically decreasing the difference between the safe and warning signals, thresholds can also be obtained.*

Immunization with Freund's Adjuvant or other compounds that may cause irritation:

Refer to the ACUC Standard Immunization Protocols distributed as part of the FSU Basic Training Course materials for research investigators for more information. The protocols are available from the LAR office. A statement under this section, that the ACUC Standard Immunization Protocols will be followed, is generally sufficient to address this issue.

The use of Freund's Adjuvant in any form should be considered a painful procedure. A description similar to the sample provided here is appropriate.

Sample statement: *"Pain associated with the use of Freund's Adjuvant will be minimized by following the ACUC Standard Immunization Protocol which calls for using 0.1 ml or less inoculum per subcutaneous injection site. The use of pain relieving drugs for this procedure is considered more stressful to the animal than the Freund's Adjuvant injection."*

Paralyzing Agents:

As stated in the Animal Welfare Act, a paralytic drug is a drug which causes partial or complete loss of muscle contraction and which has no anesthetic or analgesic properties, so that the animal cannot move, but is completely aware of its surroundings and can feel pain. The use of paralytics should be fully described including discussion of measures to insure adequate anesthesia. The Animal Welfare Act indicates paralytic drugs will not be used without anesthesia. The use of paralyzing agents should be fully described under this section and justified under Section 8.

SECTION 8 - POTENTIAL DISCOMFORT, DISTRESS OR PAIN

All potentially painful, distressful or discomfoting procedures as described in Section 7 should be justified in this section.

For each item that is applicable, justification under this section should include a statement as to why the procedure is essential to the research proposal. It is not necessary to redescribe the procedure, the monitoring techniques, or measures to minimize the pain or distress. Reference to these items in Section 7 should be made.

Sample Statement: *The use of dietary restrictions as described in Section 7 is essential to aid in training the animal to perform the required task(s) for food reward. Literature searches as described in Section 9 have not revealed any alternative procedures. Monitoring procedures and restriction techniques that are used are described in Section 7.*

SECTION 9. - ASSURANCES

SECTION 9.a.

This section addresses the Animal Welfare Act requirement that, "The principle investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources, e.g., the Animal Welfare Information Center, used to determine that alternative were not available..."

The FSU ACUC requires that all animal use proposals, regardless of the species used, comply with USDA Policy #11 and Policy #12. When painful, potentially painful or stressful procedures are to be used, an appropriate written narrative must be provided in section 9a. The narrative should be such that the ACUC can readily assess whether the search topics were appropriate and whether the search was sufficiently thorough.

Reduction, replacement, and refinement (the three R's) must be addressed, not just animal replacement.

Sample answer to Question 9.a.

REQUEST FOR ACUC REVIEW OF PROPOSED VERTEBRATE ANIMAL USE

9. ASSURANCES:

9a. Are proposed procedures painful or potentially painful? YES

if YES, please complete the remainder of section 9a; if NO, proceed to 9b;

You must provide adequate information to the ACUC to assure the committee that alternatives to painful (or potentially painful) procedures were considered and are either not available or cannot be used. Your response must include:

- the databases searched or other sources consulted
- the date of the search and the years covered by the search
- the key words and/or strategy used by the PI when considering alternatives or descriptions of other methods and sources used to determine that no alternatives were available to the painful or distressful procedure.

Databases: *circle those used* Agricola / Biosis / Medline / PsycFirst / ArticleFirst / Other (list):
Current Contents

Journals and/or other sources consulted (list): AWIC

Date of search: December 18, 1997

Years covered by search: January 1, 1994 through date of search

Keywords used: Key words were rat, behavior, feeding, pineal gland, obesity; 123 entries were found. These were reduced to 17 by searching the results for the key words non-animal model, computer model and in vitro. Of these 17, after reading abstracts, 4 copies of articles were obtained and reviewed.

Describe the results of the search and whether alternatives were found: No references were found in the literature search that indicated alternatives for animal use or alternatives to the described surgery are available.

If alternatives are available and not used, provide the ACUC with an explanation as to why alternatives cannot be used: na

SECTION 9.b.

This section addresses the Animal Welfare Act requirement that, "The principal investigator has provided written assurances that the activities do not unnecessarily duplicate previous experiments."

The FSU ACUC requires that this assurance be provided in section 9b and include, at a minimum, these specific elements:

- the databases searched or other sources consulted,

- the date of the search and the years covered by the search,
- the key words and/or search strategy used by the Principal Investigator when considering that the research is not unnecessarily duplicative.

The narrative should be such that the IACUC can readily assess whether the search topics were appropriate and whether the search was sufficiently thorough.

Sample answer to Question 9.b.

REQUEST FOR ACUC REVIEW OF PROPOSED VERTEBRATE ANIMAL USE

9. ASSURANCES:

b. Are the proposed animal procedures duplicative of previous research? YES _____

If YES, please explain why it is necessary to duplicate the previous research.

NO _XXX_ If NO, please describe the methods and sources used to determine that the research is not duplicative.

Databases: *circle those used* Agricola / Biosis / Medline / PsycFirst / ArticleFirst / Other (list):
Current Contents

Journals and/or other sources consulted (list): Colleagues and other experts in the field

Date of search: December 18, 1997

Years covered by search: January 1, 1994 through date of search

Keywords used / search strategy: Key words were rat, behavior, feeding, pineal gland, obesity; 123 entries were found. These were reduced to 9 by searching the results for the key words in vitro, organ culture, statistical model, computer model. Of these 9, after reading abstracts, 3 copies of articles were obtained and reviewed.

Describe the results of your search: The literature search and discussions with colleagues provided no evidence that these studies are duplicative.

Alternately, provide a written narrative as to the methods and sources assuring the ACUC that the research is not unnecessarily duplicative.

SECTION 9.c. - ASSURANCE THAT NECESSARY PERMITS FOR THE TAKING OF ALL WILD-CAUGHT ANIMALS HAVE BEEN OBTAINED FROM THE APPROPRIATE FEDERAL/STATE PERMITTING AUTHORITY

If this section is applicable, provide the name of the permitting agency and the permit number.

SECTION 10 - ASSURANCE THAT THE TRAINING OF ANIMAL-RELATED PERSONNEL IS APPROPRIATE FOR THE EXPERIMENTS PROPOSED

There is an increasing level of concern that the qualifications of investigators and technicians performing various procedures be documented. You should maintain a list of all personnel who will be working on the project and describe what specific procedures they will perform and their qualifications to perform that procedure. This is especially important in the case of surgery. You should be prepared to provide this information to the ACUC if requested.

This assurance is designed to meet specific requirements of the Animal Welfare Act regulations and the PHS Policy. Information and assistance in accomplishing the proper training is available from LAR. All personnel are minimally required to complete the FSU Basic Training Course and receive the Basic Training Course materials. It is the responsibility of the Principal Investigator to insure that all persons involved with the proposed animal study receive adequate training before the animal use begins. Your positive response to this question indicates to the ACUC that you have fulfilled this responsibility.

SECTION 11 - ASSURANCE OF OCCUPATIONAL HEALTH AND SAFETY

The National Institutes of Health (NIH) require that each university receiving federal support for research involving vertebrate animals must have a Medical Monitoring Program for personnel with substantial animal contact. Substantial animal contact is considered to be animal contact that involves a reasonable possibility of zoonotic disease exposure. Following the guidelines of the NIH and working in conjunction with the Leon County Public Health Physician, Florida State University developed such a program, called the FSU Medical Monitoring Program for Vertebrate Animal Users. The purpose of the program is to provide a mechanism for the diagnosis, treatment, and reduction of diseases transmitted from animal to man (zoonotic diseases).

It is the responsibility of the Principal Investigator to insure that all persons involved with the proposed animal study and have substantial animal contact are enrolled in the FSU Medical Monitoring Program. Your positive response to this question indicates to the ACUC that you have fulfilled this responsibility.

SECTION 12 - ASSURANCE ON REGULATIONS AND GUIDELINES

Familiarity with the relevant regulations and guidelines pertaining to using animals in research or teaching is essential as it not only impacts your research, but the entire research program at FSU. If you are unfamiliar with the guidelines and regulations, your research and the research program at FSU may be jeopardized. Contact LAR staff if you need any assistance with the regulations and guidelines. Your positive response to this section gives the ACUC assurance that you are familiar with the pertinent regulations and guidelines.

Appendix 1

d) IACUC review of activities involving animals.

(1) In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing. Provided however, that field studies as defined in part 1 of this subchapter are exempt from this requirement. Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements:

- (i) Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals;
- (ii) The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and has provided a written narrative description of the methods and sources, e.g. the Animal Welfare Information Center, used to determine that alternatives were not available;
- (iii) The principal investigator has provided written assurance that the activities do not unnecessarily duplicate previous experiments;
- (iv) Procedures that may cause more than momentary pain or slight pain or distress to the animal will:
 - (A) Be performed with appropriate sedatives, analgesics or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time;
 - (B) Involve, in their planning, consultation with the attending veterinarian or his or her designee;
 - (C) Not include the use of paralytics without anesthesia;
- (v) Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure;
- (vi) The animals' living conditions will be appropriate for their species in accordance with part 3 of this subchapter, and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by the attending veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied;
- (vii) Medical care for animals will be available and provided as necessary by a qualified veterinarian.
- (viii) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures;
- (ix) Activities that involve surgery include appropriate provision for pre-operative and postoperative care of the animals in accordance with established veterinary medical and nursing practices. All survival surgery will be performed using aseptic procedures, including surgical gloves, masks, sterile instruments and aseptic techniques. Major operative procedures on non-rodents will be conducted only in facilities intended for that purpose which shall be operated and maintained under aseptic conditions. Non-major operative procedures and all surgery on rodents do not require a dedicated facility, but must be performed using aseptic procedures. Operative procedures conducted at field sites need not be performed in dedicated facilities but must be performed using aseptic procedures;
- (x) No animal will be used in more than one major operative procedure from which it is allowed to recover, unless:
 - (A) Justified for scientific reasons by the principal investigator, in writing;
 - (B) Required as routine veterinary procedure or to protect the health or well-being of the animal as determined by the attending veterinarian; or
 - (C) In other special circumstances as determined by the Administrator on an individual basis. Written requests and supporting data should be sent to the Administrator, APHIS, USDA, 6505 Belcrest Road, Room 268, Hyattsville, MD 20782;
- (xi) Methods of euthanasia used must be in accordance with the definition of the term set forth in 9 CFR part 1, #1.1 of this subchapter, unless a deviation is justified for scientific reasons, in writing, by the investigator.

Proposals and significant changes must contain:

- (1) Identification of the species and the approximate number of animals to be used;
- (2) A rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used;
- (3) A complete description of the proposed use of the animals;
- (4) A description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, including provision for the use of analgesic, anesthetic, and tranquilizing drugs where indicated and appropriate to minimize discomfort and pain to animals; and
- (5) A description of any euthanasia method to be used.

SUMMARY OF THE ANIMAL CARE AND USE COMMITTEE PROCEDURES

I. ANIMAL USE DESCRIPTION (AUD) PROTOCOL REVIEW

1. AUD protocols for animal research or teaching should be submitted to the ACUC Secretary. The deadline for ACUC consideration for the month is the first working day of that month.
2. A preliminary review of the AUD protocol will be reviewed by LAR's Director, attending veterinarian, and ACUC Secretary. Any suggested changes are discussed with the principal investigator. The AUD protocols are distributed to the ACUC members four calendar days prior to the ACUC meeting. Exceptions to the established procedure may be possible by requesting an accelerated review (see below).
3. The ACUC meets and reviews the AUD protocol.

II. REPEATED PROTOCOL REVIEW

Protocols lasting more than one year are reviewed at intervals appropriate for the species employed. For species covered by the USDA, an annual review of the protocol by the ACUC is required. For all vertebrate species, PHS Policy requires a tri-annual protocol review.

1. Approximately two months in advance of the date when a repeat review must be conducted, the ACUC Secretary will send a Repeat Review Form to the Principal Investigator.
2. Submission deadlines, veterinarian review, distribution and ACUC consideration are identical to the new AUD protocols. The ACUC receives and reviews the Repeat Review Form, copies of the original approved protocol and any Repeat Reviews and/or Significant Changes that have occurred since the original approval of the AUD protocol.

III. SIGNIFICANT CHANGE REVIEW

Proposed changes in AUD Protocol procedures should be reviewed to establish whether the changes constitute a "Significant Change" as determined by the ACUC. If the proposed changes are considered Significant Changes, ACUC approval must be secured prior to initiating the changes.

1. Requests for Significant Changes follow the same procedures, deadlines, veterinary review, distribution, and committee consideration as new AUD protocols and Repeat Reviews. Exceptions to the established procedure may be possible by requesting an accelerated review (see below).
2. Requests for Significant Changes should be submitted on a Significant Change form provided by the ACUC office. The ACUC receives the Significant Change form, copies of the original approved protocol, and any Repeat Reviews and/or Significant Changes that have occurred since the original approval of the AUD protocol.

IV. ACCELERATED REVIEW FOR PROTOCOL REVIEW AND SIGNIFICANT CHANGE REQUESTS

Accelerated review may be requested for AUD protocols or significant changes. It is anticipated that accelerated review will be requested in few cases, for example, when a development in on-going research indicates that a significant change be implemented quickly to improve the quality of the research. When the Principal Investigator checks the Accelerated Review option on a Significant Change form, the following procedure is followed:

1. After preliminary review by the attending veterinarian, the Significant Change review form or AUD protocol is distributed to the full committee through a prearranged rapid distribution system. Committee members are encouraged to provide the ACUC secretary with information as to how to contact them if they are out of town. The ACUC is also provided copies of the original approved protocol and of any Repeat Reviews and/or Significant Changes already in the files for this protocol.
2. When the accelerated request is distributed, committee members are informed that the review will be conducted by a subcommittee consisting of the University Veterinarian and one other committee member designated by the Chair provided full committee review is not called. Committee members will have a maximum of 48 hours to consider the significant change or AUD protocol request. During this time, the members are invited to direct comments and questions about the request to the University Veterinarian or the ACUC Chair. If, during the 48 hour period, any member of the ACUC calls for a full committee review, the accelerated review process will be terminated. The significant change or AUD will then be placed on the agenda for the next scheduled ACUC meeting.
3. If no ACUC members call for a full committee review, the committee votes on approving the significant change or AUD protocol. A unanimous vote by the subcommittee is required for approval. The accelerated review request will be placed on the review agenda of the next ACUC meeting for confirmation of approval. If confirmation is not agreed upon by the ACUC, the approval can be rescinded or modifications required.
4. The Principal Investigator is promptly informed of all developments related to the accelerated review process.

ACUC ADMINISTRATIVE PROCEDURES RELATING TO REVIEWS

1. A majority vote of a quorum of the ACUC members is required for AUD protocol approval (except in the case of accelerated review).
2. If the AUD protocol is approved, the ACUC Secretary prepares the paperwork for approval which is signed by the ACUC Chair and the University Veterinarian. Copies are distributed to the Principal Investigator and the original is placed in the official ACUC files. If applicable, a letter of notification of approval is sent to the Principal Investigator for forwarding to the granting agency, and a copy is sent to Contracts and Grants.

Appendix 2

3. If the submission is not approved:
 - * the ACUC may require modifications in writing that can be approved by a designated reviewer
 - * the ACUC may require modifications or clarifications in writing that must be approved by the full committee
 - * the ACUC may withhold approval, in which case it will notify the Principal Investigator in writing, stating the reasons. The Principal Investigator will then be given the opportunity to respond in person or in writing, at which time the ACUC may reconsider, with documentation in the ACUC minutes.

4. Suspension of approval: The ACUC may suspend an activity not being conducted in accordance with the description provided by the Principal Investigator. Suspension requires a majority vote of a quorum at a convened meeting of the ACUC.

Animal Care and Use Committee Significant Change Form

Principal Investigator:

Date:

Campus Address:

Telephone:

Department:

ACUC Protocol Number:

Protocol Title:

I wish to make significant changes in this protocol as described below or in the attached and I request ACUC review. (Identify attachment only by protocol # and date).

Principal Investigator signature _____ Date _____

Appendix 3

GUIDELINES FOR REPORTING "SIGNIFICANT CHANGES" TO PROPOSALS FOR VERTEBRATE ANIMAL USE

NIH guidelines and USDA regulations require that any significant change in a protocol that has previously been approved by the Animal Care and Use Committee (ACUC), be reported to and reviewed by the ACUC. This list is not exhaustive but is intended as a guide to the type of changes that the ACUC might regard as "significant changes" requiring ACUC approval.

Proposed significant changes to approved procedures should be submitted to the ACUC before they are instituted. If in doubt whether a proposed change is "significant" from the point of view of animal welfare, please call the University veterinarian or the Chair of the ACUC.

EXAMPLES OF CHANGE IN ANIMAL USE PROCEDURES THAT COULD AFFECT ANIMAL WELFARE AND SHOULD BE REVIEWED BY THE ACUC:

1. Change in procedures that will result in more than momentary or slight pain or distress.
2. Change in method of anesthesia, sedation or analgesia.
3. Change in protocol that would require animals to be fed, housed or cared for in a way that is not standard for that species, or does not meet that species' minimum requirements.
4. Change in experimental protocol that would require more than momentary physical restraint of the conscious animal, e.g., chairing of primates, or use of other devices to physically restrain the subject while the experiment is in progress.
5. Change in protocol where death becomes the experimental end point. For purposes of this criterion, death is defined as natural death resulting from experimental conditions (rather than euthanasia at a time when a set of criteria recognized as the end point is met).
6. Change in protocol that would eliminate or restrict an animal's access to veterinary care.
7. Change in protocol that would require an animal to undergo more than one survival surgery. Any addition of surgery to a protocol that did not previously including surgery.
8. Changes in method of euthanasia: e.g., (a) from a chemical or inhalant method to a physical method (b) from any method to decapitation without anesthesia (c) from an AVMA recommended method to a method not specifically recommended.
9. Change of species.
10. Significant increase in number of animals used over that projected: specifically, an increase of 20% for projects approved for greater than 20 animals, or an increase of 3 animals for projects approved for 6 to 20 animals, or, an increase of 1 animal for projects approved for 5 or fewer animals.

EXPLANATION FOR CATEGORY E LISTING

This report must accompany the ACUC Animal Use Description (AUD)
to support Category E Listing

ACUC#: _____

Principal Investigator: _____

Animal Use Description Title: _____

Number and Species of Animals Listed in Category E. Use separate form for each species:

Species: _____ Number: _____

Brief description of project including reason(s) for species selection:

Justification for unrelieved pain or distress:

Signature of Principal Investigator _____

Date: _____

Signature of the ACUC Chair: _____.	Date: _____.
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