

**MIDDLE GEORGIA STATE UNIVERSITY
ANIMAL CARE COMMITTEE REVIEW FORM**

A Grant, Contract Application or complete proposal must accompany this form in order to be reviewed and receive approval by the IACUC.

**PLEASE ALLOW AT LEAST 4 WEEKS FOR PROCESSING THIS FORM.
This form must be typed.**

Complete this form, sign it, and send it to Dr. John Pattillo (john.pattillo@mga.edu), Chair of the IACUC.

IACUC approval of this protocol review form is necessary prior to animals being obtained, housed or manipulated for research or teaching purposes. IACUC approval of activities conducted on animals outside of GA prior to their arrival to MGA is also necessary.

This form should be used for new protocols, and for renewing protocols at the end of each third year approval period. Please answer each question. If the question does not apply to your research, respond with an 'N/A'. Do not answer a question by referring to your response to another question.

I. Administrative Section:

Investigator's Name: _____

Department: _____

Work Phone(s): _____

Emergency Phone(s) or secondary contact information: _____

E-mail: _____

Funding Source: _____

Fund Number: _____

II. Application Information:

Title of Application: _____

Type of Project (research/teaching): _____

Length of Project: _____

Project Ending Date: _____

Is this application: ___ for a new protocol?
 Animal Protocol Number: _____
 (will be assigned)

 ___ for an amendment to an existing protocol?
 Protocol # _____

 -- for continuing renewal of an existing protocol?
 Previous protocol #) _____

III. Rationale & Purpose of Project:

A. Scientific Summary (<250 words; Include rationale and goal of research project)

B. Layperson's Descriptions (language suitable for release to a newspaper; <250 words)

IV. Animal Use Information:

A. Rationale for the use of animal(s) for the proposed procedures versus availability of other less invasive procedures, tissue culture, computer simulation etc:

1) Living animals are required for this project because:

(Check each line)

Yes No

- a. Complexity of the processes studied cannot be duplicated/modeled using in vitro models
- b. Not enough information known about processes being studied to design non-living models
- c. Pre-clinical studies in living animals are necessary prior to human testing
- d. This study requires tissue harvested from animals prior to in vitro testing
- e. Currently this is the best method to accomplish the required teaching objectives
- f. Populations are being studied in natural or semi-natural environments
- g. Animal behavior is being studied
- h. Other (please specify):

2) This species was selected because:

- a. Anatomy, physiology, behavior or agent susceptibility of species uniquely suited to the study
- b. Lowest phylogenetic species providing adequate size, tissue, or anatomy for proposed study
- c. This species provides a particularly good model for the human or other animal disease or process
- d. Previous studies which form the background for this project used this species
- e. The objective of this study is to provide information for the target species
- f. Other (please specify):

B. Type(s) of animals to be used:

C. Number of animals to be used:

- D. Justification of the numbers of animals to be used (The IACUC requires a power calculation be provided or an explanation why a power calculation is not feasible for this project. Complete one or more of the following to justify the number of animals you will use. For experimental designs with multiple groups/treatments, it is suggested that a table of animal numbers per group be provided.):
- 1) This is a pilot/feasibility study (a total of 12 or more animals typically indicate that a project is not a pilot); describe how numbers are estimated:
 - 2) The group size was determined using a statistical package (for these calculations, specify the package, effect(s) size, variation used, and power level expected. If multiple response variables are to be measured, the power calculation should be based on the most critical measures):
 - 3) This is a teaching protocol (specify species, number of animals and number of students so that the IACUC can understand the relationships):
 - 4) This study involves tissue or cells harvested from animals for in vitro studies (explain the number of animals requested for the amount of tissue needed to obtain a specified level of precision desired, or if an experiment involving the tissue samples will be conducted as part of this protocol, provide power calculations as described in (2) above:
 - 5) This study involves breeding animals (list number of breeding adults used/number of offspring produced each year. Note these experiments will need to submit separate protocols.
 - 6) This is a study of feral or wild animals where animals will be captured and released attempting to maximize sample size within logistical constraints. Describe, and please suggest a level of precision necessary to obtain useful information and the sample size required to obtain this precision:
 - 7) This is an observational, non-manipulative study in that animal numbers will be not captured or their behavior will not be interfered with and animal numbers cannot be predicted:
 - 8) Sample size are government driven or agency mandated (provide appropriate references):
 - 9) Other: (describe in detail):

V. Description of Protocol:

(In all cases, list the room number of where these procedures will be performed)

A. Procedures not involving surgery:

B. Procedures involving surgery:

1. Brief description of the surgical procedures: (Detailed procedures must be in either the Grant Application or Protocol.)

a. If multiple major operative procedures are performed, justification is required.

2. Appropriate sedation, analgesia and anesthesia:

a. If anesthetics are administered in combination with paralytic agent(s), justification is required:

3. Post-procedure care:

4. Estimation of levels of pain and distress experienced by animals to be used, and have alternatives to painful procedures been considered (Indicate which level(s) apply for each species. If listing more than one, indicate how many animals at each pain level. Example: B (20 mice) and C (15 mice). If an animal is used for multiple procedures, count it in the most painful category):

<p>C. USDA PAIN CATEGORIES: A painful procedure is defined as any procedure that would reasonably be expected to cause more than slight or momentary pain and/or distress in an animal to which that procedure is applied.</p> <p>Animals exhibiting signs of pain, discomfort, or distress such as decreased appetite/activity level, decreased mobility, adverse reactions to physical contact, open sores/necrotic skin lesions, abscesses, lameness, conjunctivitis, corneal edema, and photophobia are expected to receive appropriate relief unless written scientific justification is provided in the protocol and approved by the IACUC.</p> <p>Category B: Breeding, conditioning only, or holding colony.</p> <p>Category C: No more than momentary or slight pain or distress and no use of pain-relieving drugs: or no pain or distress. Examples: euthanized for tissues, observation under normal conditions, positive rewards, routine injections (not Freund's Adjuvant), tattooing, blood sampling.</p> <p>Category D: Pain or distress appropriately relieved with anesthetics, analgesics and/or tranquilizing drugs or other methods for relieving pain or distress. Examples: Needle biopsy, non-survival or survival surgeries, terminal cardiac blood collection, exposure of blood vessels for catheter implantation, induced infections or antibody production.</p> <p>Category E: Unrelieved pain or distress. Examples: toxicological or microbial testing or infectious disease research that requires continuation until clinical symptoms are evident or death occurs, application of noxious stimuli, prolonged restraint, use of paralyzing drugs for restraint, infliction of burns or trauma.</p>	B	C	D	E
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For additional information regarding pain and distress go to the end of the form * and see: <http://grants2.nih.gov/grants/olaw/olaw.htm>

D. Criteria and process for timely intervention, removal of animals from a study or euthanasia if painful or stressful outcomes are anticipated:

E. Duration and methods of treatment(s):

F. Method of euthanasia (must list method even if procedure is carried out by CBR personnel) or disposition of animals:

For information regarding the AVMA Panel on Euthanasia see: <http://grants2.nih.gov/grants/olaw/olaw.htm>

G. Unusual housing and husbandry requirements (e.g., restraining devices, radioactive materials/other biohazards, infectious diseases):

H. Safety of working environment for personnel:

VI. Additional approvals:

A. Will animals or their wastes or experimental agents be, or possibly be:

1. Biohazardous (infectious agents or rDNA/transgenics) Yes No

If yes, identify agents or rDNA use, describe potential risk to personnel/environment and risk management steps you've taken.

Cite NSBC approval number _____ Date _____

2. Radioactive Yes No

3. Use of controlled drugs Yes No

4. Carcinogenic to humans or other animals Yes No

VII. Training and experience in appropriate techniques of researchers, co-workers, and animal handlers (list procedures/protocols in which individual has trained/experience with (Example – PI – anesthesia experience – isofluorane, tribromoethanol injections – i.p., i.v., s.q. surgery – arterial catheter placement):

	Name, Degree, Certification	Training History	Experience	Protocols Procedures e.g. animal handling, injections, anesthesia, surgery, euthanasia	Individual species authorized to use on this protocol
PI					
Staff & students					

VIII. For research proposals on laboratory maintained vertebrates, researchers should provide documentation that the proposed procedures do not necessarily duplicate previous experiments. This documentation should include a written statement and a list of specific literature search parameters used (include at least two databases searched, keywords used in searching, number of matches or hits using these keywords). Potential databases include but are not limited to: Medline, Pubmed, Agricola, Biosis, Embase, CAB Abstracts, MedBioWorld, Highwire Press.

Alternatives include methods that (1) refine existing tests by minimizing animal distress, (2) reduce the number of animals necessary for an experiment, or (3) replace whole-animal use with in vitro or other tests. When ascites production is used to produce antibodies, justification needs to be given as to why in vitro systems cannot be used.

Date search performed:

Keywords used:

Period covered by search:

Names of databases searched:

Number of matches or hits:

Did the search reveal applicable alternatives?

Yes

No

If yes, please explain:

My signature certifies that the above information is true and correct.

_____ Date

_____ Principal Investigator

IX. Committee recommendation: _____Approved_____Disapproved

Disapproval based on the following:

Required Signatures:

Committee Official

Date

IACUC Chairperson

Date

Institutional Veterinarian

Date

* USDA Classifications and Examples

Classification B: Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes.

Examples:

- Breeding colonies of any animal species (USDA does not require listing of rats, mice, birds) that are held in legal sized caging and handled in accordance with the *Guide* and other applicable regulations. Breeding colony includes parents and offspring.
- Newly acquired animals that are held in proper caging and handled in accordance with applicable regulations.
- Animals held under proper captive conditions or wild animals that are being observed.

Classification C: Animals upon which teaching, research, experiments, or tests will be conducted involving no pain, distress, or use of pain-relieving drugs.

Examples:

- Procedures performed correctly by trained personnel such as the administration of electrolytes/fluids, administration of oral medication, blood collection from a common peripheral vein per standard veterinary practice (dog cephalic, cat jugular) or catheterization of same, standard radiography, parenteral injections of non-irritating substances.
- Euthanasia performed in accordance with the recommendations of the most recent AVMA Panel on Euthanasia, utilizing procedures that produce rapid unconsciousness and subsequent humane death.
- Manual restraint that is no longer than would be required for a simple exam; short period of chair restraint for an adapted nonhuman primate.

Classification D: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will be used.

Examples:

- Surgical procedures conducted by trained personnel in accordance with standard veterinary practice such as biopsies, gonadectomy, exposure of blood vessels, chronic catheter implantation, laparotomy or laparoscopy.
- Blood collection by more invasive routes such as intracardiac or periorbital collection from species without a true orbital sinus such as rats and guinea pigs.
- Administration of drugs, chemicals, toxins, or organisms that would be expected to produce pain or distress but which will be alleviated by analgesics.

Classification E: Animals upon which teaching, experiments, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs will adversely affect the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests.

Examples:

- Procedures producing pain or distress unrelieved by analgesics such as toxicity studies, microbial virulence testing, radiation sickness, and research on stress, shock, or pain.
- Surgical and postsurgical sequella from invasion of body cavities, orthopedic procedures, dentistry or other hard or soft tissue damage that produces unrelieved pain or distress.
- Negative conditioning via electric shocks that would cause pain in humans.
- Chairing of nonhuman primates not conditioned to the procedure for the time period used.

NOTE REGARDING CLASSIFICATION E: An explanation of the procedures producing pain or distress in these animals and the justification for not using appropriate anesthetic, analgesic or tranquilizing drugs must be provided on **Attachment 1**. This information is required to be reported to the USDA, will be available from USDA under the Freedom of Information Act, and may be publicly available through the Internet via USDA's website.