REQUEST FOR MODIFICATION OF PREVIOUSLY APPROVED IACUC PROTOCOL

Institutional Animal Care and Use Committee of Morehouse School of Medicine/Atlanta University Center

720 Westview Dr., SW
HGB B-B56   http://www.msm.edu/research/research_centersandinstitutes/CLAR.aspx   Office: 404-752-1724
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FOR OFFICE USE ONLY		IACUC #	
Date Received:	Date Approved:	Reviewers:	

For modifications to an existing protocol, please explain the nature of the changes and provide the following information. IACUC may administratively approve as a minor modification, approve following committee review, or request a full application if modification is considered major.

1.	Protocol Number:	
2.	Title:	
3.	Principal Investigator Name:	
4.	Principal Investigator Signature:	
5.	Date:	
6.	Biohazard (check one)	☐ Yes ☐ No
7.	Radiation (check one)	☐ Yes ☐ No

When providing answers, please type within the cell provided. If no cell is provided, you will see an arrow (➔), please start answer to right of this arrow. These areas will expand as you type. For all tables, to add another row, just press the TAB key from within the last cell of the last row.

8. **Summary of Modification**: Briefly state if changes are in procedures, drugs/agents administered or instrumentation, or new species, funding, personnel, etc. And describe changes:
➔

    a.   Justification if altered from original statement in IACUC application:
➔

    b.   Specific Aims if altered from original:
➔

9. **Is there a new funding agent**/new grant title associated with the modifications? (Verification of approval is provided to OSP for funding agencies.) Provide the name of grant PI, grant title, funding agency.
➔

10. **PERSONNEL:**
    Credentials must be on file at the IACUC office. Please indicate if they are on file. If they are not on file, please complete the Credentials Verification Form and attach to the application.

1. List ALL Personnel that will work on this Protocol/Project. Verify Credentials and Certifications are on file or attached:						
Name	Campus Address	Office Phone	Office Fax	Email	File	Attached

    2. Will this person(s) be performing surgery or any anesthetic procedures? No ☐   Yes ☐
    If yes, please provide the date they have completed CLAR surgical training or the scheduled date of training.
    Date: _____

11. **Change of Species**: Please provide the rationale for the change in species. (Make sure that all personnel working with the new species have their experience and qualifications on file via a current Credentials form.)
➔

12. **If new procedures are to be added** (as described in answer to question 6), indicate potential painful/distressing effects on animals, means of monitoring these effects, actions to be taken and experimental endpoint. <mark>**Please update the Protocol Synopsis for this protocol.**</mark>
➔

13. **Number of and Justification for Animals** to be ADDED to original Protocol/Project.
➔

14. **Number of animals** in each stress level in the **protocol modification request**.   Be sure that each species involved in the Protocol/Project is accounted for. (Added animals only)

Class B. Animals bred, conditioned, or held for use in teaching, testing, experiments, research or surgery but not yet needed for such purposes.

Species	Year 1	Year 2	Year 3	Total

This is the estimated number of animals that will either be used for breeding or their offspring will be maintained for experimental use.

Class C. Non-Painful/Non-Stressful: Animals upon which teaching, research, experiments or tests will be conducted involving no pain, distress or use of pain-relieving drugs. These are routine procedures such as blood sampling, tattooing and injections. Euthanasia is performed in accordance with the recommendations of the AVMA Report on Euthanasia. Polyclonal antibody production and procedures involving administration of an anesthetic, analgesic or tranquilizing drug to an animal for short term restraint purposes to perform a procedure that involves no pain or distress may be considered level C, including other routine procedures causing only slight or momentary discomfort such as: venipuncture, injections, and the use of non-inflammatory adjuvants.

Species	Year 1	Year 2	Year 3	Total

Indicate procedures that may result in pain or stress under some circumstances, such as inflammatory reactions to injections or in response to infectious agents, even if these reactions are generally not expected.
Indicate how animals will be monitored for such occurrences.
➔

Class D. **Painful/Stressful WITH Analgesia/Anesthesia/Tranquilizers**: 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. In addition, terminal surgical procedures in which the animals are euthanized before recovering from anesthesia are considered level D.

Species	Year 1	Year 2	Year 3	Total

Class E. Painful/Stressful WITHOUT Pain or Stress Relieving Measures: 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 would adversely affect the procedures, results, or interpretation of the teaching, research, experiments, surgery, or test. An explanation of these procedures and reasons why appropriate drugs were not used must be justified in the Animal Care and Use Protocol.

Species	Year 1	Year 2	Year 3	Total

1) Describe the anticipated pain or distress for each species listed in stress levels **D**. and **E**. from section F1.
➔

2) Describe how pain or distress will be monitored for each species:
➔

3) List who will monitor or observe animals. **Animals must be monitored at least daily.**
➔

4) Indicate schedule of monitoring. **A record of monitoring must be maintained and posted.**
➔

5) For animals in stress level **D.**, describe the interventions and/or the dose, frequency and type of analgesic drugs or tranquilizers to be administered if pain or distress occurs for each species:
➔

6) For animals in stress levels **D.** and **E.** studies that may result in debilitation (such as infectious diseases or toxicity testing), describe specific criteria, for each species, which will determine when animals should be euthanized to prevent undue pain or distress:
➔

7) Annual Report to United States Department of Agriculture of **Stress Level E Procedures** for vertebrate animals **other than rats, mice**, birds, and amphibians**:** MSM IACUC must submit an annual report to the USDA describing the use of regulated species that are classified in stress level **E**. Briefly describe, **in lay terms**, all procedures on each regulated species listed in stress level **E** above. State why pain or distress relieving measures cannot be used (your summary will be will be included in the report to the USDA).

➔

15. **Lack of non-painful, non-stressful alternatives**: If any animals are listed in stress levels **D.** and **E.** in question 14 above, the **Principal Investigator** is **required** by law to document that **alternatives** to procedures that may cause pain or distress to animals have been **considered**. The USDA and Public Health Service support the three R's (Replace, Reduce and Refine) as guidelines for the choice of species and number of animals to be used.   **(The alternative search is not the same as the duplication search.)**

   For more information on the alternatives search http://altweb.jhsph.edu/

   (See instructions for USDA Policy). Link to page posted on web site.

   http://awic.nal.usda.gov/nal_display/index.php?info_center=3&tax_level=1&tax_subject=184
    Link to worksheet on alternatives search.

   If investigators have difficulty with this section they can send protocols (or description of the activities, expected outcomes, etc) by e-mail to awic@ars.usda.gov at the USDA Animal Welfare Information Center (AWIC). AWIC will run the search and send results back to the investigator, usually within one week.

   a. A computer-assisted literature search is considered by the USDA to be the best method to check for **non-painful, non-stressful alternatives**. Therefore, you are required to describe the date, keywords and the database(s) searched below for each species. (Keep copies of the search results in your files.)

Species➔   Species➔   Species➔

Database(s):

Date(s) of Search:

Key Words used to determine alternatives:

Date Range:

Results - List the three most relevant results and explain why these are not applicable to achieving the aims of your study.

b. Are less painful and/or less stressful alternatives available?	Yes ☐	No ☐

c. If YES, justify (for each species) why they are not going to be used.

➔

._____   _____

Signature, Principal Investigator   Date

_____   _____   _____

Name of Principal Investigator   Phone number   Department

APPROVED

_____   _____

Signature, Chairperson MSM/AUC, IACUC, or CLAR Director   Date

Protocol Synopsis

PI:		Protocol #:	
Title:			
Species:		**Approval Date:**	
Expiration Date:			
Research Synopsis: The summary (Indicate study goals and procedures to be performed)			

Special Information	Yes	No	Specify
Average Daily Animal Number			
Breeding			
Delayed Weaning (> 21 days)			
Geriatric Animals (>12 months)			
Genetically Engineered/Mutant Animals			
Genotyping			
• *Tail or Other*			
Identification Methods: *Ear Tag, Ear Punch, Microchip, Tattoo, Toe Clip*			
Individual Housing			
Non-Standard Caging			
• *Wheel, metabolism, sterile, other*			
Cage Change Frequency			
No/Limited Environmental Enrichment			
• *Please Specify*			
Food/Water: *Restrictions or special diet, medicated water*			
• *Please Specify*			
Animal Removed from Animal Facility			
• *If yes, where?*			
• *Reason for removal*			
Animals Returned to Animal Facility			
• *If yes, where?*			

Survival Surgery			
• *Post-operative Analgesia*			
• *Please Specify Drug*			
• *Frequency*			
Terminal Surgery			
Behavior Testing			
Special Information	**Yes**	**No**	**Specify**
Tumors			
• *If yes, please specify location:*			
Injections			
• *IP, IV, SQ, IM, ID (specify all that apply)*			
• *Location*			
• *Volume*			
• *Frequency*			
Administration of Substances Which Could Cause Pain			
• *Location*			
• *Volume*			
• *Frequency*			
• *Signs to monitor*			
Oral Gavage			
• *Volume*			
• *Frequency*			
Blood Collection			
• *Method*			
• *Volume*			
• *Frequency*			
Anesthesia			
• *Type*			
• *For what procedures?*			
Illness (*Illness is possible or expected?*)			
• *Monitoring frequency*			
• *Endpoint (How long animals are kept post-procedure?)*			
• *Euthanasia criteria*			
• *Euthanasia method*			
• *Secondary method*			
• *Disposition(Euthanasia, Transfer, Adoption)*			

Bio-Hazards			
• *Biosafety Level*			
• *PPE*			
• *Procedures*			
Chemical Hazards			
• *PPE*			
• *Procedures*			
• *Others*			

Personnel				
Name	**Office Phone**	**Email**	**Cell Phone/Pager**	**Emergency Contact?**
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐
				Yes ☐ No ☐