Howard University
Proposal for Laboratory Vertebrate Use in Research, Teaching or Testing

Form IACUC A: Use this A Form for new proposals, renewals, revisions, 3 year de novo continuations, and addenda or continuations with significant changes. See Instructions for completing the IACUC Forms at www.howard.edu/orrc . Sections of this form will expand to accommodate text as needed.

Note: Incomplete, hand-written or unsigned forms will be returned. Print, sign, date and submit form to the Ofc. of Regulatory Research Compliance, 1840 7th Street, NW, Suite 309

IACUC Contact Information: Email: theorrc@howard.edu Ph: 202 865-8597
Fax: 202-232-5286

I certify that this form is completed truthfully, that I and all persons who handle animals on this project are or will be appropriately trained, that the IACUC will be notified before any changes are made in animal use or care that this study will be conducted humanely in accordance with University and applicable federal regulations, and that a reasonable good-faith effort was made to assure that the proposal activities do not unnecessarily duplicate previous experiments. Applicable IACUC guidelines will be followed.

Principal Investigator Signature - *Must be a HU Faculty Member* Date

For Committee Use Only (Rev 02/2007)			
Date Received:			
IACUC No.:			
Child No.:			
FCR	☐	Date	
FCR Approval Date			
SciMerit	☐	Date	
AdDelRv	☐	Date	
AdDelRv AutoApproval			
	☐	Date	
IBC	☐	Date	
Final Approval Date			
Expiration Date			
Notes:			

Principal Investigator (PI) and Proposal Information

First Name	Middle Init	Last Name	Department	Building	Room No.
PI Phone No.		PI Email	PI"s Technician In Charge	Technician Phone No.	

Proposal Title		Project Period (yrs)	
Will grant be peer-reviewed for scientific merit by the funding organization? For grants that will not be peer-reviewed or student research proposals, prepare a research plan following the outline in item IX. of *Instructions for Submission of Proposal for Laboratory Vertebrate Use in Research or Teaching* and submit it with this proposal.		Yes ☐	No ☐

Funding Source						
NIH ☐	NSF ☐	Dept ☐	Other ☐ (Specify):			
Proposal Type:	New ☐	Renewal ☐	Revision ☐	3 yr De novo ☐	Addenda ☐ or Continuation ☐ w\ Significant Changes	
Is proposal identical to a proposal sent to other sponsor(s)?	Yes ☐	No ☐	If „yes" enter IACUC No.:			
If this is not a new proposal provide the age\year of work\research\teaching\or testing for this proposal:						Year __ of __

1. A. Animal Use Information (*Enter information for each species of animal to be used)*

Enter species of animal to be used and complete section I. for each species

For each species: 1. Enter total number of animals requested (New) or approved for your project each year. In last column of **I.** enter total for all years. **2.** If this is **not** a New proposal enter additional animals requested under the appropriate year; if New enter zero. In last column of **I.** enter total for all years. **3.** Add the total for **1**. and **2**. In last column of **I.** enter total for all years. **4.** If this is not a New proposal enter number of animals used to date; if New enter zero. In last column of **I.** enter total for all years. **5.** Subtract D from C. In last column of **I.** enter total for all years. **6.** and **7.** Enter average number of animals (to be) housed simultaneously. **8.** and **9.** Enter average housing days per animal.

I. Total Animals Per Year and Total Animals for All Years Per Species							**II. Average No. Housed Simultaneously**		**III. Average Housing Days Per Animal**	
Species 1		**Breed or Strain(s)**								
Total Animals Per Year for each species of animal [See instructions above (*).]	Year 1	Year2	Year 3	Year 4	Year 5	Total for Years 1-5	6. Current Approved or Requested (if New)	7. Change Request (Enter 0 if New)	8. Current Approved or Requested (if New)	9. Change Request (Enter 0 if New)
1. No. Approved\Requested										
2. Additional No. to be added										
3. New Total (Add A + B)										
4. No. Used To Date										
5. No. Remaining for Use (Subtract D minus C)										

I. Total Animals Per Year and Total Animals for All Years Per Species							II. Average No. of Animals Housed Simultaneously		III. Average Housing Days Per Animal	
Species 2		**Breed or Strain(s)**								
Total Animals Per Year for each species of animal [See instructions above (*).]	Year 1	Year2	Year 3	Year 4	Year 5	Total for Years 1-5	6. Current Approved or Requested (if New)	7. Change Request (Enter 0 if New)	8. Current Approved or Requested (if New)	9. Change Request (Enter 0 if New)
1. No. Approved\Requested										
2. Additional No. to be added										
3. New Total (Add A + B)										
4. No. Used To Date										
5. No. Remaining for Use (Subtract D minus C)										

I. Total Animals Per Year and Total Animals for All Years Per Species							II. Average No. of Animals Housed Simultaneously		III. Average Housing Days Per Animal	
Species 3		**Breed or Strain(s)**								
Total Animals Per Year for each species of animal [See instructions above (*).]	Year 1	Year2	Year 3	Year 4	Year 5	Total for Years 1-5	6. Current Approved or Requested (if New)	7. Change Request (Enter 0 if New)	8. Current Approved or Requested (if New)	9. Change Request (Enter 0 if New)
1. No. Approved\Requested										
2. Additional No. to be added										
3. New Total (Add A + B)										
4. No. Used To Date										
5. No. Remaining for Use (Subtract D minus C)										

1. B.1. Location of Animal Housing and Use (Check or Enter Information below)		
Location of Animal Housing:		
Veterinary Services ☐	Just Hall ☐	Other On Campus IACUC Approved Site ☐ (Specify Bldg, Room # Below)
Room #	Room #	
1. B. 2. Location of Animal Use:		
Veterinary Services ☐	Just Hall ☐	Other On Campus IACUC Approved Site ☐ (Specify Bldg, Room # Below)
Room #	Room #	

1. B. 3. Describe transportation from site of animal housing to site of animal use if not in Veterinary Services or Just Hall.		
1. B. 4. Is authorization requested to hold animals outside of IACUC approved housing more than 12 hours? If „yes", justify below.	Yes ☐	No ☐
1. B. 5. Will animals be housed outside of HU? If answer is „yes" provide outside housing information below.	Yes ☐	No ☐
Outside Housing of Animals: Complete this part if animals will be housed outside of HU:		
Institution Name:		
Institution Address:		
Institution Assurance No.		
Name of IACUC Chairperson of other institution	Phone No.	
Has your proposal been approved by IACUC at the other institution? Pending ☐	Yes ☐	No ☐
Is the other institution AAALAC accredited?	Yes ☐	No ☐
1.C. 2.Special Housing /Care Requirements (Indicate any special housing, diet, light cycle, carcass disposal requirements)		

1. C.2.Enrichment: OLAW and AAALAC have placed a high priority on animal enrichment which may be defined as the system of animal environmental and social management that promotes species specific behaviors. Laboratory animal facilities implement enrichment through animal species group housing, positive interaction with animals during husbandry and care and the provision of caging accessories or toys, nesting material and nutritional compatible food treats that promote chewing, taste enhancement, foraging, nest building and burrowing. And while enrichment items such as nesting material for mice appears to have a benign impact on mice and definitely promotes species-specific behavior, other more complex enrichment paradigms may change trained or untrained animal behaviors or background biochemical and physiological parameters. This may unfavorably impact on-going studies. Yet, it is important that enrichment be actively pursued for the benefit of the animal. With this as a background, Veterinary Services will provide all rodents with environmental enrichment (rodents - group housing, mice – nesting material, rats – PCV pipe or tunnels) and all other species with manipulata (cage toys for cats, ferrets and swine) food treats and group housing of compatible animals. Rodents may be provided nonnutritive chew toys or treats. Researchers must decide whether to opt in or out of enrichment or specify restrictions for animal on their proposals. Complete the following for each species:

Species 1	☐ I place no restrictions on enrichment for animals on my study as summarized
	☐ I place restrictions on my study as follows: ☐ No group housing ☐ No cage habitat enrichment items (nesting material or tunnels or huts) ☐ No toys ☐ No non-nutritive food treats ☐No nutritive food treats ☐ Other (specify):
Species 1	☐ I place no restrictions on enrichment for animals on my study as summarized
	☐ I place restrictions on my study as follows: ☐ No group housing ☐ No cage habitat enrichment items (nesting material or tunnels or huts) ☐ No toys ☐ No non-nutritive food treats ☐No nutritive food treats ☐ Other (specify):
Species 1	☐ I place no restrictions on enrichment for animals on my study as summarized
	☐ I place restrictions on my study as follows: ☐ No group housing ☐ No cage habitat enrichment items (nesting material or tunnels or huts) ☐ No toys ☐ No non-nutritive food treats ☐No nutritive food treats ☐ Other (specify):

1. D In vivo Use of Hazardous Agents/Materials in Animals:

Select the Animal Biosafety Level (ABSL) of Animal Work:	**ABSL0** ☐	**ABSL1** ☐	**ABSL2** ☐	**ABSL3** ☐

Check all that apply below:

None ☐	Recombinant DNA ☐	Radioisotope ☐	Carcinogen ☐	Infectious Agent ☐	Select Agent ☐	Other ☐

Identify agent (s) for each .1 D. Item checked. Attach MSDS for chemicals. Indicate BSL level for Biohazards. Give RG Category for recombinant agents. For information on using „Hazardous Agents or Materials" or „Select Agents" in animals refer to Section XII. of the *Instructions for Submission of Proposal for Laboratory Vertebrate Use in Research or Teaching.*

Is there risk to Veterinary Services (VS) personnel, research personnel, animals on other experiments or the environment posed by substances in the diet, air (dust or aerosol), water, research or caging equipment or by living or dead animals and their secretions or excrement? Note: If answer is "Yes", identify risk(s) below; and submit application to the appropriate Safety Committee(s) [Institutional Biosafety Committee (IBC) or Radiation Safety Committee (RSC). Also complete the attached *IACUC Safety Form for In vivo Use of Hazardous Materials/Agents in Animals*. It is the responsibility of the Principal Investigator to assure that copies of the [IBC and RSC Committee Letter of Approval are submitted to the IACUC. It is also the responsibility of the Principal Investigator to assure that applications are submitted to the appropriate safety committee for work to be carried out under this proposal.	No ☐	Yes ☐

Safety Committee (SC) Approval Status

IBC: ☐Approved on ☐Not Approved ☐ Pending | **RSC:** ☐Approved on ☐Not Approved ☐Pending

1. E. Animal Handling/Animal Surgical Training and Experience: List all persons (including Principal Investigator, students, research and lab technicians) who will handle the animals and perform experimental techniques.

Training Record

A copy of the *NRC Guide for the Care and Use of Laboratory Animals and the AVMA Panel on Euthanasia* is available in my laboratory. I have also reviewed requirements and policies on the IACUC website at www.huiacuc.howard.edu. If your response is „No" to any item the IACUC at 202 806 5340 and request copies.	**Yes**☐	**No**☐

Animal Handlers	Completed LATA Online Training and Certification		Experience With Relevant Species
	Yes	No	(yrs)
	☐	☐	
	☐	☐	
	☐	☐	
	☐	☐	
	☐	☐	
	☐	☐	
	☐	☐	

	☐	☐	
	☐	☐	
	☐	☐	
	☐	☐	

Animal Surgeon(s)	Experience with Surgical Procedure		Experience With Surgical Procedure
	Yes	No	(yrs)
	☐	☐	
	☐	☐	
	☐	☐	
	☐	☐	
	☐	☐	
	☐	☐	
	☐	☐	
	☐	☐	
	☐	☐	
	☐	☐	
	☐	☐	
	☐	☐	

Indicate what provisions will be made to instruct and train project personnel who have little of no experience in the surgery or procedures to be performed.

1. F Project Purpose, Hypothesis and Benefit: Please use lay person terminology since nonscientists may access this information. Avoid or define first use acronyms.

Purpose

Hypothesis

Benefits

Progress Report: If this **not a new proposal** provide a progress report below.

2. A. Description of Animal Use: Check ALL that apply.

Behavior Study	☐	No Surgery	☐	Unalleviated Pain, Stress or Distress	☐
Restraint > 15 min/day	☐	Nonsurvival Surgery (acute)	☐	In Vivo rDNA Study	☐
Food Deprivation	☐	Minor Survival Surgery	☐	Mouse Ascites Model	☐
Water Deprivation	☐	Major Survival Surgery	☐	Infectious Disease – Animal Pathogen	☐
Pain Study	☐	Multiple Survival Surgery (same animal)	☐	Infectious Disease- Human and Animal Pathogen	☐
Immunization Study	☐	Sacrifice for Tissue Collection Only	☐	Metabolic Disease	☐
Death as an Endpoint	☐	Environmental Manipulation	☐	Tumor Study	☐
Use of Paralytic Agents	☐	Drug Efficacy/Toxicity Study	☐	Toe Clip Identification of Neonatal Mice	☐
GLP Study	☐	Dogs, Cats or Nonhuman Primates	☐	Endangered Species (See XI of *Instructions*)	☐
Device Evaluation	☐	Rodent Breeding Required	☐	Pregnant Dams To Be Ordered and Used: Approval for Abbreviated Quarantine Requested	☐
Paralytic Drug Used	☐	Field Study	☐		

2. B. Restraint: This refers to restraint of a conscious animal that exceeds 15 minutes a day (not to unconscious anesthetized animal).

Will animals be restrained? ☐ No ☐ Yes

If restraint exceeds 15 minutes a day, identify restraint device, justify use, indicate restraint time per session and whether animals will be acclimated to restraint.

Estimate level of pain, stress and/or distress experienced by animal due to restraint:

☐ (none) 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 (severe)

2. C. Blood Collection: For each animal group indicate anatomical site, frequency, and volume withdrawn per collection time. Refer to IACUC Guidelines for collection limits. A sedative or anesthetic agent is required for retro-orbital sinus or intra-cardial collection: Provide agent and dosage information below.

2. D. Surgical Procedures: See VIII of *Instructions* to estimate level of pain, stress and/or distress (P,S,D).

OR Location	Animal			Identify operative procedure and number of times to be performed on a single animal.	Actual P,S,D Level Experienced by the Animal: (none) 0,1,2,3,4 (severe)			
	Species \Strain	Sex	No. Animals		Operative		Post-Op	
					PSD Level	Duration	PSD Level	Duration

2. E. Non-Surgical Procedures: See VIII of *Instructions* to estimate level of P,S,D. **Important Note:** Researchers employing disease production models, tumor studies or immunization note that while the injection of a pathogen, neoplastic cells or adjuvant may be almost painless, the postprocedural consequences of disease (pneumonia, neurological disorders, progressive dehydration and debilitation, malignancy, etc.) or inflammation at the site of injection (post Freunds abscessation, ulceration) may be moderate to severe.

Procedural Room Location	Animal			Identify procedure and number of times to be performed on a single animal	Actual P,S,D Level Experienced by the Animal: (none) 0,1,2,3,4 (severe)			
	Species \Strain	Sex	No. Animals		Procedural		Post-Procedural	
					PSD Level	Duration	**PSD Level**	Duration
2. F. Does the non-surgical procedure result in permanent physical or physiological impairment? If „yes", describe and justify below.					Yes ☐		No ☐	

2G. Detailed Description of Surgical and Non-Surgical Procedure(s) Note**:** Describe in detail exactly what happens to the animal from the start of research use to euthanasia.

2. H. Pain Alleviating Drug Administration (PAD):

☐ **No PAD will be administered because (select response below):**

☐ None, pain low or brief ☐ Drugs will interfere with study (Justify Below)*

Provide justification for not administering PAD to alleviate more than low or brief pain and specifically how they will interfere with study.*

Presurgical \ Preprocedural Drugs Used (Ex: Acepromazine prior to obtaining blood from the ear veins of rabbits, pre-emptive analgesia, etc.) Provide drug name, dosage, route, experimental phase when drug will be given (e.g. 30 minutes prior to performing surgical or nonsurgical procedure.)

Surgical or Procedural Drugs Used: For each procedure listed (under 2.D and 2. E.) provide names, routes, frequency of administration and dosages of drugs used to relieve pain, stress or distress.

Postsurgical or Postprocedural Drugs Used: For each procedure listed (under 2.D and 2. E.) provide names, routes, frequency of administration and dosages of drugs used to relieve pain, stress or distress and experimental phase when drug will be given (e.g. If there is evidence of pain, 48 hrs post-op)

2. I. Assessment, Prevention and Minimization of Adverse Effects(AE):

Adverse Effects (AE): List potential adverse effects of each surgical or nonsurgical procedure.

Detection of AE: Describe how AE will be assessed.

Prevention and Minimization of AE: Describe how AE will be prevented (e.g., analgesics, euthanasia, transfusion, acclimation to restraint)

Provide justification for not preventing/minimizing AE (if applicable)

2. J. Alternatives Search for USDA Covered Species: Stipulate USDA Study Category (C, D or E) potential for any group of animals that may experience pain, stress or distress during this approval year. Please note that USDA-APHIS considers the statement, "No alternatives found" (or equivocal statement) to indicate that the alternatives search was, in a majority of cases, inadequately carried out.

☐ I am using, rats, mice, birds or amphibians.

☐ I am using a USDA covered species under the following USDA Category (Check one):

☐USDA Category C*	☐USDA Category D**	☐USDA Category E***

***Category C:** No pain/distress and no use of pain-relieving drugs (routine procedures, injections and blood sampling)
****Category D:** Pain/distress for which appropriate anesthetic, analgesic, or tranquilizing drugs are used
*****Category E:** Pain/distress for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs are withheld due to adverse effects on procedures, results or interpretations.

Alternatives Search for USDA Covered Species See relevant sections of the IACUC *Guidelines for Investigators Using Animals in Research or Teaching* for information on completing this section. Attach search and retain a copy for your records until project ends.

Databases Searched: ☐Current Research Information Service ☐Medline ☐BIOSIS Previews ☐ CAB Extracts ☐EMBASE ☐Agricola ☐ Pascal ☐ Toxline ☐ Altweb ☐ SCOPUS ☐Other (specify):

Period Searched (last 10 years)	

Key Words Used

Other Sources Consulted (must attach documentation)

Alternatives Found

Conclusions

Three R's (Reduction, Refinement and Replacement): Incorporation of Procedures for Reduction, Refinement and/or Replacement:
Definitions: Reduction: Minimize the number of animals used. **Refinement:** Employ techniques that reduce pain and distress. **Replacement:** Substitute animal with nonanimal or animals that are less sentient or lower on the phylogenetic scale. Indicate instances wherein all or some of the 3R"s were incorporated into your proposal.

Reduction: Have you incorporated measures to reduce the number of animals to be used in your proposal?	Yes ☐	No ☐

If response is „Yes" indicate below how this will be accomplished.

Refinement: Have you incorporated measures to reduce or minimize pain and distress in your proposal?	Yes ☐	No ☐

If response is „Yes" indicate below how this will be accomplished.

Replacement: Are you using less sentient animals or animals lower on the phylogenetic scale in your proposal?	Yes ☐	No ☐

If response is „Yes" indicate below how this will be accomplished.

3. Justification of Animal Use

3.A. Justify the use of animals vs. non-animal methods.

3.B. Justify the choice of species

3.C. Define the groups of animals and number of animals in each group. Include a description of the statistical analysis you plan to conduct to answer each of your hypotheses (chi-square, t-tests, correlations, logistic regression, linear regression, etc).

3.D. Justify the number of animals. If you are testing statistical hypotheses, include the statistical assumptions you made to estimate the sample size needed to answer each of your hypotheses (alpha and beta type errors, one-sided or two-sided tests, power, expected standard deviation of your measure(s), expected difference between groups/expected strength of the association. Include the statistics your sample size estimates are based on (chi-square [one-group or two-group], t-tests, correlations, etc). If your study objective is to estimate a statistical quantity, describe the desired level of precision to be achieved (e.g., "We wish to estimate the proportion of mice expressing gene XYZ +/- .10, where it is expected to be about .50."). If the study objectives are non-statistical, provide a justification for the number of animals required in order to meet those objectives.

3. D.1. Did you use a sample size software program? If yes, name the software program below.	☐ No	☐ Yes

3.D.2. Did a statistician assist you with your sample size estimates? If yes, name the statistician below.	☐ No	☐ Yes

4. Euthanasia Method (If applicable list drug, dose and route)

Method:
Drug: Dose: Route:

Decapitation or cervical dislocation performed without sedation must be scientifically justified below. It is the responsibility of the PI to ensure that decapitation or cervical dislocation is performed by properly trained personnel.

Supplemental Information: Additional information may be pasted below as required. Be sure to identify topic clearly. Example: the literature search.

IACUC Safety Form for In vivo Use of Hazardous Materials/Agents in Animals Submit this Form ONLY if using hazardous agents or materials. It must also be reviewed and approved by the relevant Safety Committee.
Enter IACUC Protocol Number (if available) and Proposal Title Below:
1. Identify hazardous material of agent (biological, chemical, radioactive, other)
2. For biological agents indicate the Biosafety Level (BSL 1,2 or 3); for rDNA agents indicate the Risk Group (RG 1, 2 or 3):
3. Indicate whether the agent(s) pose(s) a safety hazard to humans, animals, both or the environment. Describe each agent listed under No. 1 separately.
4. Complete the following section in sufficient detail for the committee to render a sound judgment. Failure to provide relevant information may delay approval and may constitute a serious breach of professional behavior. Attach an MSDS if available.
4.a. Source(s) of Exposure: Confine response to issues related to in vivo use. (e.g. Stock or dispensed material, animal breath, dander, fur, excrement or secretions, caging or research equipment, hood surface, aerosolized materials from centrifugation, sonication, stirring, mixing or other manipulation in the vivaraium, etc).
4.b. Assessment of the Risk: Source(s) of Exposure: Confine response to issues related to in vivo use. (e.g. Does inoculation of material pose a risk, transport of agent to or from vivarium? Does handling\contact with the animal or bedding pose a risk and how long, etc.) For biological agents follow BMBL risk assessment procedures, for chemicals base assessment on the MSDS, for recombinant DNA agents follow the NIH Guidelines for use of Recombinant DNA in research, for radioactive compounds follow RSC guidelines.
4.c. Control or Minimization of the Risks Cited under 4.b.: Confine response to issues related to in vivo use. (e.g. Engineering controls, personal protective equipment (PPE), handling and secondary containment of stock material, storage, decontamination methods and disposal): Control must be consistent with federal, local and University regulations, requirements or guidelines.
4.d. If medical screening or testing and health surveillance procedures have been recommended or are required briefly describe procedures below.
4.e. Indicate means of decontamination of agent in case of a spill or accidental release. Method must comply with Safety Committee and federal regulatory requirements.
4.f. Indicate training (including seminars to be given for research and /or VS staffs if required) /advising/supervision of research staff.
4.g. Written Warnings/Information (e.g. MSDS, BSL, RG, etc.): Provide a mock-up of the written warnings/information that must appear on the vivarium room door for protection of humans and or animals.
I affirm by my signature that the above information is true and complete. Type or Print Name Principal Investigator Signature Date