July 08, 2014

UCB
INSTITUTIONAL ANIMAL CARE
AND USE COMMITTEE (IACUC)
NIH ASSURANCE #A4107-01
Animal Utilization Proposal Form

Protocol #
14-07-3748

Protocol Title: Type your study title here...

Approval Period: Draft

Important Note: This Print View may not reflect all comments and contingencies for approval. Please check the comments section of the online protocol.

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* * * Personnel Information * * *

Principal Investigator

(Must have PI status or Exceptional PI status at UC Berkeley)

Name
EMP-FACULTY TEST

Title
Professor

Email
test@uclink.berkeley.edu

Office Phone
+1 (510) 643-1234

Lab Phone

Emergency Phone

Department

Mail Code
94720-3804

Campus Mailing Address

Working with animals on this protocol? Yes No

If "Yes" complete the following:

Species to be Used (common name):

Brief description of proposed procedures:

All individuals listed on an Animal Use Protocol (AUP) are required to complete the Collaborative Institutional Training Initiative (CITI) course entitled, "Investigators, Staff and Students - Basic Course" and the Animal Exposure Questionnaire (AEQ). See the Training and Education and Animal Occupational Health and Safety Program (AOHSP) policies for more information.

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* * * Species * * *

Species to be Used

Common Name	Mouse
Genus & Species	Mus musculus
Strain or Breed	list or attach strains
Animal Sex	Male
Weight Range	-
Age Range	-
Source	OLAC Approved Vendors
Proposed Housing Location	OLAC Vivarium
Room Number	
Maximum number of animals for three year project period	500

Note: If breeding animals, the maximum number should include breeders plus all offspring produced.

Common Name	Rat
Genus & Species	Rattus norvegicus
Strain or Breed	list or attach strains
Animal Sex	Both
Weight Range	-
Age Range	-
Source	OLAC Approved Vendors
Proposed Housing Location	OLAC Vivarium
Room Number	
Maximum number of animals for three year project period	100

Note: If breeding animals, the maximum number should include breeders plus all offspring produced.

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* * * Are You Using? * * *

Are you using?

NOTE: The questions below are used to identify special circumstances where: 1) additional oversight by regulatory agencies may be required 2) coordination with campus compliance committees may be required 3) personnel health and safety issues need to be addressed

1. Collaboration with Other Institution(s) Yes or No

Animal transfers or changes in animal ownership between UC Berkeley PIs and collaborators at other institutions must comply with the ACUC policy on Changes in Animal Ownership and ACUC Guidelines on Animal Transportation.

2. Hazardous Agent(s) in Laboratory Animals

a) Recombinant DNA Yes or No

The introduction of recombinant DNA/RNA into animals and the generation of transgenic animals require approval by the UC Berkeley Committee for Laboratory and Environmental Biosafety (CLEB) prior to ACUC approval. For guidance, please refer to the EH&S Biosafety Program web site .

Recombinant Material

1. Recombinant Material	
2. Source	
3. BUA Number	
4. Use Location	
a. Building Name	
b. Room	

Transgenic Animals

NOTE: If breeding animals create a Breeding/Genotyping Procedure and provide

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b) Infectious Agent(s) Yes or No

Use of BSL-2 or 3 infectious agents in animals (including viral vectors; human cells, tissues or bodily fluids; and infectious select agents) requires approval by the UC Berkeley Committee for Laboratory and Environmental Biosafety (CLEB) prior to ACUC approval. For guidance, please refer to the EH&S Biosafety Program web site .

c) Toxic Agent(s) Yes or No

This includes the use of carcinogens, reproductive hazards, and other biological toxins (including select agents) in laboratory animals. Standard Operating Procedures (SOPs) must be in place. For guidance, please refer to the EH&S SOP web site.

d) Human Embryonic Stem Cells Yes or No

NOTE: Use of Human Embryonic Stem Cells in animals requires approval by the UC Berkley Stem Cell Research Oversight Committee(SCRO) and CLEB prior to ACUC approval. For guidance, please refer to the SCRO web site and the EH&S Biosafety Program web site.

1. Do you have SCRO approval?
2. BUA #

3. Biological Material/Animal Product(s) Not Described Above Yes or No

NOTE: The use of biological materials in rodents must comply with the ACUC Policy on Testing Biologicals Used in Laboratory Rodents. The use of human cells, tissues or bodily fluids requires approval by the UC Berkeley Committee for Laboratory and Environmental Biosafety (CLEB) prior to ACUC approval. For guidance, please refer to the EH&S Biosafety Program web site.

a) Controlled Substance(s) Yes or No

NOTE: The Principal Investigator and any individuals using controlled substances in animals must be registered with EH&S prior using these agents. For guidance, please refer to the EH&S Controlled Substance Program web site.

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4. Radiological Agent(s)

Yes or No

NOTE: Use of radiological agents in animals, radiation producing devices or lasers requires an approved Radiation Use Authorization(RUA) or Laser Use Registration (LUR) be in place prior to ACUC approval. For further guidance, please refer to the EH&S Radiation Safety Programs web site or Laser Safety Program web site.

5. Non-pharmaceutical Grade Compounds

Yes or No

NOTE: Federal regulations require the use of pharmaceutical grade compounds in animals used for research and teaching unless those compounds are not available or are otherwise inappropriate for the aims of the proposed animal use. Please refer to the ACUC Policy on Use of Non-Pharmaceutical Grade Compounds

6. Field Study or Wildlife Study

N

NOTE: Additional procedure-based information for field studies is requested under the Protocol Information section of the Protocol.

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* * * Funding Sources * * *

Funding Checklist

If the research is not funded, check the "Not Funded" box below.
If the research is funded, add the funding source to the appropriate table below.

NOTE: Only the Principal Investigator (PI) of the grant or subcontract can add his or her own SPO Funding information in this section. The PI of the grant or subcontract must also be listed in the Personnel Information section of the protocol in one of the following roles: Principal Investigator or Faculty Sponsor, Student or Postdoctoral Investigator, Co-Principal Investigator, Administrative Contact, or Other Contact. Training Grants can be added by anyone in one of the aforementioned roles. For step-by-step instructions, see XX

Not Funded

SPO - Funding

SPO ID	Sponsor	Sponsor Award ID	Prime Sponsor	Project Title
026732-002	American Cancer Society, Inc.	PF-09-131-01-DMC		Molecular Mechanism of DNA Unwinding by the Eukaryotic Replicative Helicase

SPO ID	026732-002
Sponsor Award ID	PF-09-131-01-DMC
Sponsor	American Cancer Society, Inc.
Prime Sponsor	
Funding Status	
Principal Investigator (PI)	
Co-Investigator(s)	
Administrative Unit	The California Institute for Quantitative Biosciences (QB3)
Project Title	Molecular Mechanism of DNA Unwinding by the Eukaryotic Replicative Helicase
Amount	$138,000

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* * * Rationale * * *

Rationale

As you answer the questions in this section, please use language that can be understood by a layperson. r Avoid overly technical terms and define abbreviations.

1. STUDY OBJECTIVES

a) **What is the overall aim and purpose of this research?**

Describe overall aim & purpose

b) **How will the information gained be important to human or animal health, the advancement of knowledge, or the good of society?**

Describe benefit to human or animal health, advancement of knowledge, good of society

2. RATIONALE FOR USE OF ANIMALS

a) **Why do you need to use animals? Discuss why non-vertebrate alternatives (e.g., tissue culture, invertebrate animal models, computer simulations) are inappropriate or implausible to answer your scientific questions.**

Describe why there is no alternative to using animals.

b) **Why have you selected the proposed species?**

Describe why you have to use this species.

3. JUSTIFICATION OF ANIMAL NUMBERS

For complete instructions and guidance on how to complete the section on justification of animal numbers, please refer to the ACUC guideline on Justification for Animal Numbers found on the ACUC website.

a) **How did you determine that the numbers provided in the Species section of this protocol are the smallest number of animals needed to fulfill the study goals over a three-year period? Please use the table below to graphically describe for reviewers how you arrived at your animal numbers. Regardless of species, please briefly describe the study aim(s) included in your protocol and complete the table below, for the three-year period of the protocol. Note: Study aims may consist of multiple procedures. For breeding colonies, enter these as a line item, with the total consisting of breeding stock plus offspring NOT used in any studies.**

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Regardless of species, please number the procedures in your protocol and complete the table below:

Animal Groups for Procedures

Procedure Title	Sugery
Number of groups (Control)	1
Number of groups (Experimental)	5
Number of animals per group	5
Number of replications needed	1
Total number of animals needed	30

b) **Please justify the proposed number of animals being used:**

Provide justification for the number of animals proposed.

c) **Method Used to Determine Sample Size (check all that apply):**

This is a pilot study, as similarly established studies do not exist. The proposed study will use a small number of animals to determine the feasibility of a larger study.

X **Studies cited in the literature; please provide the literature citations here or as an attachment:**

Site or attach references.

X **Statistical estimates; please describe the power analysis and all other statical analyses used:**

Provide statistical methods.

Previous experience by this PI. Please describe and cite references here or as an attachment.

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* * * Procedures * * *

Surgical Procedure

Surgical Procedure	Surgical Procedure	**Procedure Title:**	Surgery #1
Species:	Mouse (OLAC Vivarium)		
Pain/Distress Category:			D
Approximate number of animals to be used in this procedure for a THREE-YEAR period:	30	**Was a veterinarian consulted (for D or E studies)?:**	Y
Use Site:	UC Berkeley campus	**Building Name:**	NAF
		Room Number:	45

---

* * * Surgery Information if surgery is performed at Yale University site* * *

For guidance, please refer to the ACUC Guidelines for Anesthesia and Analgesia in Laboratory Animals, Guidelines for Surgical Procedures, Recordkeeping Guidelines for Surgical Procedures on Laboratory Animals, and Multiple Partial Ovariectomies on Xenopus (MPOX) Policy.

Specific room number where surgery is performed: NAF 45

Surgery Type: S-Survival

MULTIPLE MAJOR SURVIVAL SURGERY: The Guide defines major survival surgery as a surgical procedure that penetrates and exposes a body cavity, produces substantial impairment of physical or physiologic functions, or involves extensive tissue dissection or transection. The USDA defines a major operative procedure as any surgical intervention that penetrates and exposes a body cavity or any procedure that produces permanent impairment of physical or physiological functions.

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If a major surgical procedure is performed on an animal prior to obtaining it (e.g., surgerized animals obtained from a vendor), and a subsequent major survival surgical procedure is performed on the same animal, this is considered Multiple Major Survival Surgery.

Will this project include Multiple Major Survival Surgery (MMSS)? N

PLEASE NOTE: If multiple major survival procedures are to be performed, you will be asked for specific justification in Procedure Relationships section of this form.

Number of animals that will undergo MMSS per year:

---

* * * Procedure Description * * *

Procedure Description

Procedure Description

Please list any clinical effects or changes from the normal health and behavior of an untreated animal which may occur as a result of this procedure.

List any clinical effects

Describe post procedure monitoring that will be performed.

Describe post procedure monitoring

What criteria will be used to determine if animals exhibiting clinical or behavioral changes should be euthanized?

Describe humane endpoints

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* * * Surgeon Details * * *

Surgeon Details

Surgeon Name	Specific Surgical Exp.	Describe the previous experience and/or training plan to assure surgical proficiency.
EMP-STAFF TEST	Y	Describe the previous experience and/or training

Surgeon Details

Surgeon Name
EMP-STAFF TEST

Y

Does the Surgeon have prior specific experience with this surgery on this species?

Describe the previous experience and/or training plan to assure surgical proficiency.
Describe the previous experience and/or training

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* * * Anesthetic Regimen * * *

Anesthetist(s)

Anesthetist Name	Describe previous experience and training in anesthesia.
EMP-STAFF TEST	Describe previous experience and training in anesthesia.

Anesthetist(s)

Anesthetist Name EMP-STAFF TEST

Describe previous experience and training in anesthesia. Describe previous experience and training in anesthesia.

Concentration CFU/ml (if possible)*

BAR Number

X Respiratory Rate
X Heart Rate
X Body Temperature
Blood Pressure
Corneal/Palpebral Reflex
X Pedal Reflex
Capillary Refill
PO2
ETCO2
Other (Describe)

Describe recordkeeping methods during anesthesia. For guidance, please refer the ACUC Recordkeeping Guidelines for Surgical Procedures on Laboratory Animals.

Describe recordkeeping methods during anesthesia

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Anesthetic Agents

Agent Name	Dosage (in mg/kg if possible)	Route
Isoflurane	Dosage	Inhalation (IN)

Anesthetic Agents

Agent Name Isoflurane

Dosage (in mg/kg if possible) and volume Dosage
Route Inhalation (IN)

Paralytic Agents

Other premedications not already listed above

Agent Name	Dosage (in mg/kg if possible)	Route	Duration and Frequency of Administration
Ocular Lubricant	1	topical (Topical)	Duration and Frequency of Administration

Other premedications not already listed above

Agent Name Ocular Lubricant

Dosage (in mg/kg if possible) and volume 1
Route topical (Topical)

Duration and Frequency of Administration
Duration and Frequency of Administration

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* * * Peri procedure Care/Analgesics * * *

Analgesics

Agent Name	Dosage (in mg/kg if possible)	Route	Duration and Frequency of Administration
Analgesics	10	Intramuscularly (IM)	Duration and Frequency of Administration

Analgesics

Agent Name
Other
Analgesics

Dosage (in mg/kg if possible) and volume
10

Route
Intramuscularly (IM)

Duration and Frequency of Administration
Duration and Frequency of Administration

Describe what parameters will be monitored during the procedure to assure proper analgesia (e.g., respiratory rate, corneal/palpebral reflex, pedal reflex, etc.):
Describe parameters

Antibiotics or Anti-Microbials

Agent Name	Dosage (in mg/kg if possible)	Route	Duration and Frequency of Administration
Amoxicillin	10	Oral (PO)	Duration and Frequency of Administration

Antibiotics or Anti-Microbials

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Agent Name Amoxicillin

Dosage (in mg/kg if possible) and volume 10
Route Oral (PO)

Duration and Frequency of Administration
Duration and Frequency of Administration

Post-procedure Monitoring

Analgesic Agents

Agent Name	Dosage (in mg/kg if possible)	Route	Duration and Frequency of Administration
Analgesics	10	Intramuscularly (IM)	Duration and Frequency of Administration

Analgesic Agents

Agent Name Other
Analgesics

Dosage (in mg/kg if possible) and volume 10
Route Intramuscularly (IM)

Duration and Frequency of Administration
Duration and Frequency of Administration

Recovery Location Building Name NAF **Room Number** 45

Responsible Personnel
Emp-Staff

Parameters Monitored (e.g., appetite, body weight, body condition score, posture, etc.)

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Parameters Monitored

Monitoring Duration

Monitoring Duration

Monitoring Frequency

Monitoring Frequency

Describe what actions will be taken if parameters monitored fall outside normal ranges:

Describe actions

Describe any non-pharmaceutical support provided during recovery (e.g., heating pads, soft/palatable foods, food provided on cage floor, etc.):

Describe any non-pharmaceutical support

Describe record keeping/documentation methods for post-procedure monitoring:

Describe record keeping/documentation

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* * * Other Drugs Utilized * * *

Note: Pharmaceutical grade compounds must be used in animals unless those compounds are not available or are otherwise inappropriate for the aims of the proposed animal use. If proposing to use non-pharmaceutical grade compounds, please complete the appropriate questions on the "Are You Using" section of the protocol. For guidance, please refer to the ACUC policy on Use of Non-pharmaceutical Grade Compounds.

Other Drugs Agents

Agent Name	Dosage (in mg/kg if possible)	Route	Frequency
Other drugs	10	topical (Topical)	Frequency

Other Drugs Agents

Agent Name Other
Other drugs

Dosage (in mg/kg if possible) and volume 10

Route topical (Topical)

Frequency Frequency

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* * * Alternative Search * * *

For Pain/Distress Categories D or E

For any procedure that is likely to cause more than slight or momentary pain or distress, a literature search is required to determine if other methods are available that could reduce or eliminate pain or distress experienced by the animal. Instructions and examples of this literature search, appropriate databases to use, and helpful keywords can be found in the guidelines on Literature Searches for Alternatives on the ACUC website.

Search Data

Search Range	Databases Searched
	ALTBIB/ PUBMED

Search Data

ALTBIB/ PUBMED	2000-2014	
	CAB Abstracts	
	Data Base Guide - UC Davis Center for Animal Alternative Information	
	FRAME - Fund for the Replacement of Animals in Medical Experiments	
	EURL ECVAM DataBase Service on Alternative Methods to Animal Experimentation (DB-ALM)	
	NORINA Database - Norwegian Inventory of Alternatives	
	National Cancer Institute Mouse Models	
X	PUBMED - National Library of Medicine	
	CancerLit	
	MeSH (Medical Subject Headings)	
	TOXLINE - Toxicology Literature Online	
	Web of Science	
	Other	

Search Range From
2000
(YYYY)

To
2014

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(YYYY)	Search Date
04/01/2014	
(MM/DD/YYYY)	**Keywords**
Keywords	

Databases Searched

	Agricola - National Library Catalog
X	ALTBIB - Resources for Alternatives to the Use of Live Vertebrates in Biomedical Research and Testing (US National Library of Medicine)
	Animal Welfare Information Center
	ALTWEB - Alternative to Animal Testing on the Web (Johns Hopkins)

Describe the search strategies used to conduct your search.

Describe the search strategies

Provide the number of hits and summarize the findings of your search results.

Number of hits and findings

I believe there is no alternative to further reduce, replace or refine this potentially painful/distressful procedure. Based on the following references and experience, this animal model is the most appropriate for conducting my research.

Specific Relevant Citations

Relevant citations must be listed here or provided as an attachment.

Specific Relevant Citations

For category E procedures, explain why drugs or other ameliorative treatments cannot be used to fully alleviate pain/distress. Include the number of animals per year.

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* * * Husbandry * * *

If animals will be transported between facilities, laboratories or institutions (e.g., hand carried, vehicular, etc.), describe the methods and containment measures to be utilized. Transportation of animals must conform to the ACUC Animal Transportation Guidelines.

FIELD STUDIES: If animals (live or dead) will be transported to or from the field, describe how they will be transported and measures to be taken to avoid potential disease transmission to researchers and other animals. Transportation of animals must conform to the ACUC Animal Transportation Guidelines.

Please check and describe all non-standard housing requirements that apply. Provide justification for each. For guidance, please refer to ACUC's Guidance on Exceptions Regarding Housing or Husbandry of Laboratory Animals, Aquatic Frog Housing Density, Guidelines for Investigators Who Manage Mouse Breeding Programs, and Rat Housing Guidelines.

Non-standard housing requirements

Species	Cage/Pen Size	Cage sanitation interval	Wire-bottom rodent cages or grids	Animals outside dedicated animal housing for greater than 12 hours	Exemption from exercise (dogs only)
Mouse (OLAC Vivarium)					
Rat (OLAC Vivarium)					

Description of Non-Standard Housing Requirements

Please check and describe any non-standard environmental requirements, diets, husbandry equipment or animal care. Include which species are affected. For guidance, please refer to ACUC's Guidance on Exceptions Regarding Housing or Husbandry of Laboratory Animals and Fasting Animals, Special/Regulated Diets/Water/Housing Policy.

Investigator Care of Animals (describe below and provide justification). For guidance, please refer to the ACUC Guidelines on Investigator Care of Vertebrate Animals.

Non-Standard Lighting Cycles, e.g., greater than twelve-hour light or dark cycles (describe below and provide justification).

Non-Standard Housing Temperature Ranges (describe below and provide justification).

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Non-Standard Diets (describe below and provide justification). For guidance, please refer to the ACUC Fasting Animals, Special/Regulated Diets/Water/Housing Policy.

Telemetry or Tether Devices (describe below and provide justification).

Running Wheels (describe below and provide justification).

Individually Housed (describe below and provide justification).

Exemption from Standard Enrichment (describe below and provide justification). For guidance, please refer to the ACUC Environmental Enrichment Guidelines.

Other - Please describe and provide justification.

Non-standard Experimental Requirements

Complete all section below that apply. For guidance, please refer to the ACUC Fasting Animals, Special/Regulated Diets/Water/Housing Policy.

Food or Fluid restriction

Species	Food Restriction	Length of Restriction	Fluid Restriction	Length of Restriction	Reason for Restriction
Mouse (OLAC Vivarium)					
Rat (OLAC Vivarium)					

Complete all section below that apply. For guidance, please refer to the ACUC guidelines on Physical Restraint of Unanesthetized Animals.

Restraint of Conscious Animals

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Species	Type restraint (manual, commercial, manual and commercial)	Describe acclimation to restraint	Length of restraint
Mouse (OLAC Vivarium)			
Rat (OLAC Vivarium)			

Description of Restraint

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* * * Animal Disposition * * *

Please consult the ACUC Euthanasia Guidelines. Following euthanasia and prior to carcass disposal, an additional physical means of ensuring euthanasia must be performed.

Euthanasia

Species	Primary euthanasia method	Secondary euthanasia method	Route of Administration	Dosage mg/kg (if possible)
Mouse (OLAC Vivarium)	Carbon Dioxide	Cervical Dislocation	Inhalation (IN)	10
Rat (OLAC Vivarium)	Pentobarbital Overdose	Bilateral Thoracotomy	Intramuscularly (IM)	10

Euthanasia

Species Mouse (OLAC Vivarium)

Species Rat (OLAC Vivarium)

Provide specific details for carcass disposal.

Carcass disposal

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* * * Certifications * * *

Certification

As Principal Investigator, I have ultimate responsibility for this study, the protection of animal subjects, and strict adherence by all co-investigators and research personnel to federal regulations, state statutes, and University of California (UC) Office of the President (UCOP) and UC Berkeley (UCB) policies pertaining to animal use in research and teaching. I hereby assure the following:

1) As per the ACUC's Policy and Procedures on Protocol Review, any changes in the care and use of animals involved in this protocol will be promptly forwarded to the ACUC for review. Such changes will not be implemented until approval is obtained from the ACUC. I understand that the ACUC and Institutional Official (IO) have the authority to suspend a previously approved protocol if an activity is performed differently from that outlined in the protocol.

2) All procedures involving animal subjects will be performed under my supervision or that of another qualified professional listed on this protocol. Individuals listed on this protocol are qualified or will be trained to conduct procedures involving animals outlined under this proposal as per the ACUC's Training and Education Policy.

3) As per the ACUC's Training and Education Policy, all individuals listed on an this protocol have completed the required Collaborative Institutional Training Initiative (CITI) course, Investigators, Staff, and Students - Basic Course.

4) As per the ACUC's Animal Occupational Health and Safety Program (AOHSP), all individuals working on this protocol have enrolled in the AOHSP by submitting an Animal Exposure Questionnaire (AEQ). I understand that further participation in the AOHSP is voluntary unless required by the Occupational Health Physician or if the individual is working with specific species or research material.

5) The research proposed herein is not unnecessarily duplicative of previous reported research.

6) I ascribe to all of the responsibilities outlined in the ACUC's Principal Investigator Responsibilities policy.

X As Principal Investigator, I have read and agree to abide by the above obligations.
