

IACUC Protocol/Three Year Renewal Form Rev. January 2022

VERTEBRATE ANIMAL Research

Westfield State University (WSU) Institutional Animal Care and Use Committee (IACUC) serves as the IACUC for the WSU. The use of animals is essential to the teaching, outreach, and research missions of WSU. Significant benefits to the health and welfare of both animals and humans have resulted from animal use in research, and continued use is crucial to future advancements. Those who utilize animals in teaching and research are morally and legally obligated to care for them properly and use them humanely. Each faculty member, staff member, or student involved in the use of animals is directly responsible for promoting and protecting their welfare within the instructional, research, and outreach programs of WSU. The IACUC is responsible for overseeing the provisions for the care and well-being of animals used for research and educational purposes at the University and serves the public by ensuring compliance with all legal and ethical standards regarding the use of vertebrate animals in research and teaching at WSU.

Instructions

Research requiring Registration

Use this form to register research involving vertebrate animals. Animal use may not proceed until authorization from the IACUC.

Form Submittal

Submit via email to IACUC Chair, John McDonald at jemcdonald@westfield.ma.edu. Please include IACUC in the email subject line.

- This Protocol Document. **Please try to limit your answers to the space provided.** Upload separate document if you believe additional information is valuable to the committee (refer to specific questions you are addressing).
- Any attachments
- Relevant thesis or grant proposals
- Signed Proposal Approval, if part of a thesis
- Student Assurance form, if graduate student will be using project data to complete a thesis.
- Certificates of completion for all Citi training courses
- Certificate of completion of Laboratory Safety Training
- Valid copy of any Departmental of Environmental Management animal collection permits for all species described within the protocol (Unless an approved protocol is required for acquisition of the permit. Include a brief statement of this instead).
- Completed OHW Survey

Adobe Forms

- Check that you have installed the latest version of Adobe Acrobat or Reader. The link to install Adobe Reader is: http://get.adobe.com/reader.
- Download the Protocol, Mac and iOS Users, open the file using Adobe Reader rather than the Preview function built into your Mac OS. Windows users, open the file using Adobe Acrobat or Reader rather than using a web browser.
- Save the form once you have entered your information.

Training

All faculty, staff, and students listed on the protocol must complete Laboratory Safety Training with WSU Chemical Hygiene Office (Contact Jamie Herrick at jherrick@westfield.ma.edu for further information), and the on-line training courses at www.CITlprogram.org. Complete the follwing Courses in: Care and Use of Vertebrate Animals module (including any courses within the module that are specific to the species of animals as described in Section 3 of this Protocol Form).

- 1) Working with the IACUC: Introduction
- 2) About the IACUC
- 3) Federal Laws, Policies, and Guidelines.
- 4) Planning Research and Completing the Protocol Form
- 5) Personnel and Their Welfare
- 6) Special Animal Welfare Considerations
- 7) Making Changes to an Approved Animal Use Protocol

Occupational Health

All personnel (Faculty, staff and students) working with animals in research and teaching environments are required to fill out an Occupational Health and Wellness Survey (OHW), to be submitted with the protocol.

Reference Materials

- USDA/APHIS Animal Welfare Act, www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare
- The NIH Office of Laboratory Animal Welfare (OLAW), PHS Policy on Humane Care and Use of Laboratory Animals, grants.nih.gov/grants/olaw/references/phspol.htm and What Investigators Need to Know About the Use of Animals, grants.nih.gov/grants/olaw/investigatorsneed2know.pdf

IACUC Review and Approval Cycle

- IACUC approvals involving USDA covered species require annual renewals (to complete, submit an annual renewal form).
- All Protocols must be resubmitted and reviewed every 3 years
- Allow at least 4-6 weeks for protocol review, depending on the complexity of the project.



IACUC

Protocol/Three Year Renewal Form

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Section 1 - Administrative Information

REMINDER FOR MAC USERS: Complete form in Adobe Reader, not the Preview function in MAC OS. Using the Preview function will disable parts of the form.

a. Principal Investigator						
b. College / Department		_				
c.Email	d. Phone Number					
Check all the responsibilities that apply	Training Certificate(s) Uploaded Animal Husbandry Administeranestheis Perform surgery Perform euthanasia Draw blood/perform injection	sa				
e. Project Title						
f. Type of Application	New Protocol If renewal, list Three-Year Renewal Protocol Number					
g. Anticipated Research Start Date	Anticipated Research End Date					
Funding						
h. Is this project funded or being submitted for possible funding?	Yes If yes, submit an electronic copy of the grant proposal as part of your protocol package					
Funding Source	If the project is funded, is the project PHS funded? No					
Grant/ContractTitle						
Grant/Contract ID#:	Proposal Submission Date:					
Permits i. Will you be conducting any activities for which a permit is required? One which a permit is required? If yes, submit an copy of the local, state or international collection permit as part of your protocol package						
Collaboration j. Does this project involve collaborate with another institution?	If yes, submit a copy of IACUC approval from the other institution prior to the initiation of the off campus portion of the project. (Not needed for initial approval of work being conducted at WSU.					
Use of Animals in Teaching						
k. Does this project involve use of animals in teaching?	If yes, list instructor, department, course number and title, and years and semesters course will be taught.					



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Section 2 - Personnel

List all personnel associated with th	eproject						
a. Co-Investigator							
Name		Departme	ent				
Email		Phone Nu	ımber				
Check all the responsibilities that ap	oply: Training Certificate(s) Upl	oaded	AnimalHu	ısbandry	Admin	ister an est he	isa
b. Student Researcher(s) Perform surgery Performeuthanasia Draw blood/performinjection							
Name	1	Name					
Email Email							
Check all the responsibilities that ap	oply: Training Certificate(s) Upl	oaded [AnimalHu	ısbandry	Admin	isteranesthe	isa
	Perform surgery	Performe	 uthanasia	Draw b	olood/perform	injection	
Will this project be used as a thesi independent study or research pa		0,					
c. Other Personnel				Posnon	sibilities		
Name	Position	Observation	Animal		Drawblood/	Perform	Perform
		only	Husbandry		perform injection	surgery	euthanasia
Qualifications							
Qualifications							
Qualifications							
Qualifications							
Qualifications							
Qualifications			•	•		•	
Qualifications							



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Section 3 - Animal Care and Use

importance to the advancemer in layman's terms and limit yo				for amelioratio	n of disease) o	f your project. Write
b. Describe the rationale for using	animals in th	is research and t	he appropriate	eness of the spe	ecies to be use	d.
c. If more than 10 individuals of th accepted statistical principles or c http://statpages.org/#Power.						
l. Activities involving animals must not unnecessarily	○ ^{Yes} ○ No	If yes, please justify				
duplicate previous	ONO	justily				
experiments. Duplication of previous experiments?						



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Section 4 - Experimental Design

e tne aaaitionai space	provided on the followin	g page ırnecessary.	



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4a. Experimental Design cont.



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Section 5 - Animal Information

a. Animal Inventory

Common and Species Name/Strain	Source	Animal Use Classification				Total # of Animals per Year	Total # of Animals For Project (planned for next 3 years)	
		A	В	□ c	D	E		
		□ A	В	□ c	□ D	E		
		ΠA	□В	□ c	□D	E		
		A	□В	□ c	□ D	□ E		
		A	□В	□ C	□ D	E		
		A	□В	□ c	□ D	E		
 Pain/Distress Category: USDA Category under which animal use falls. The WSU Attending Veterinarian must be consulted for any animals in Category DorE. Category A - No live animal contact. This includes field observations and the use of cadavers or carcasses (this is a WSU category, not a USDA category) Category B - Animal use activities that involve only breeding, conditioning, orholding. Category C - No/minimal pain, distress, or discomfort is associated with the protocol and no pain relieving drugs or treatments are necessary. This includes routine procedures such as blood sampling, short-term restraint, injections, and euthanasia and also includes posteuthanasia procedures such as tissue harvesting. Category D - (Relieved Pain) Pain, distress, or discomfort is associated with the protocol, and pain-relieving drugs, anesthesia, or treatments are provided as part of the protocol. Category E - (Unrelieved Pain) Pain, distress, or discomfort is associated with the protocol but pain relieving drugs or treatment are withheld because their use would interfere with the scientific objectives. 								
b. Are any of the animals on this protocol species covered by the USDA Animal Welfare Act? The USDA Animal Welfare Act covers all warm blooded animals except: (1)birds, rats of the genus <i>Rattus</i> , and mice of the genus <i>Mus</i> , bred for use in research, (2) horses not used for research purposes, and (3)other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber.								



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Section 6 - Pain and/or Discomfort

If animals will be exposed to procedures that cause more than momentary or slight pain or distress (e.g., animals listed in Category **D** or **E** in Section 5), indicate below the anesthetics, analgesics, or tranquilizers to be used.

 $a. \ Use \ of \ An est hetics, \ An algesics, \ or \ Tranquilizers.$

Species	Specific Drug(s)	Dose per Kg Body Weight	Route of Administration	Frequency of Administration		
		Weight	Administration	Administration		
b. Describe procedure for monitoring animals exposure to drug?						
c. Describe procedures involving pain or distress:						
d. If you will perform painful or distressful procedures that will NOT be alleviated (i.e., Category E), please provide a scientific justification:						
e. Describe method or means to determine that receiving pain or distress would interfere with results:						
f. If you expect any unanticipated effects (including pain and distress) of your procedures or						

stimuli on the animals (e.g. weight loss, fever, poor appearance, neurological deficits or behavioral abnormalities), please describe in the space below. Describe the conditions, complications and criteria (e.g. 20% weight loss, maximum tumor size, vocalizing, and lack of grooming) that would lead to contacting the attending veterinarian or euthanasia of an animal before the expected completion of the experiment.

Note: if any unanticipated effects not described below occur during the course of the study, a complete description of those effects and any action taken in response to them must be communicated to the Attending Veterinarian and the IACUC Chair immediately. The Event Reporting Form must be submitted to the IACUC Chari within 72 hours.



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Section 7 - Animal Husbandry

a.Preferred location of animal housi (include building and room #):	ng	
b.Will your protocol require any of the Facility SOPs for feeding and housing		or husbandry conditions that deviate from normal Animal
Sterile cages	Special bedding	☐ Food regulation
☐ Wire bottom cages	☐ No bedding	☐ Waterregulation
☐ No enrichment	☐ Social isolation	☐ Special diet
☐ Other		If yes to water or food regulation, refer to IACUC Food and Water Regulation for Laboratory Animals Policy
For any condition checked above, p	please describe (include the le	ength of time required for each condition) and provide a
Maintenance Outside Animal F	acility Housing	
Complete this section if animals will b more than 24 consecutive hours (12 h		r other area not designated for housing of laboratory animals t
. Donatida la cation and describe		
 c. Provide location and describe facilities that will be used to house the animals: 		
d. Provide justification for the need to move animals outside animal facilities:		
e. Describe transportation to be used and who will transport animals:		
f. Will animals be returned to	Yes	
original animal facility?	∩ No	



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Section 8 - Alternatives

The Animal Welfare Act Regulations, Section 2.31 and USDA (Policy #11 and #12) require that a written narrative be provided by the Principle Investigator (PI) to determine whether or not alternatives exist to procedures which may cause pain or distress in animals used for teaching or research. In addition, if alternatives exist but are not used, the PI must justify why this is the case. Alternatives have been broadly defined to include: procedures that <u>reduce</u> the number of animals used (e.g., special statistical designs, sharing animals/specimens with several projects, etc.); <u>refinements</u> that decrease the pain or distress experienced by the animal; and methods that <u>replace</u> animals with non-animal alternatives or employ the use of animals with a lower taxonomic status.

a. If your protocol includes any procedures to reduce or refine, please describe briefly.			
b. If any alternatives (reducing, refining, or replacing) are available, and they are not being used, explain what they are and why they are not being used.			
c. If no alternatives (reducing, refining, or replacing) are available, please explain why.			
assertion. An electronic literatur	re search constitutes	part of the basis fo	ves are available, you must explain the basis for this r this assertion, please provide search details utilizing ve" when conducting your search.
Databases	Date of Search	Years Covered	Key Words or Search Strategy
Suggested resources for literature sources: Animal Welfare Information Center - Alternatives and Consideration of Alternatives to Painful/Distressful Procedures	e. The literature search yielded the following information (attach separate sheet if needed)		
whom the IACUC may contact	ct who are familiar w	ith the experiment	ves are available, please list one or more experts al procedures you are using and might render an Westfield faculty would be appropriate.
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Section 9 - Other Procedures

Answer the following questions regarding blood collection, restraining animals and animal stress.

a. Blood collection?	⊜Yes ⊝No	If yes , refer to <u>IACUC policy of Blood Collection</u>
Volume of Blood Drav	v Frequency and Number o	of Samples Collection Site
b. Restraining animals with me	chanical device? Yes No	
If yes, describe the type of restraint (e.g., rabbit plastic restrainer, tethering)?		
If yes, what is the duration of restraint (e.g., 1 to 2 hours, overnight)?		
If yes, provide a scientific justification for the restraint.		
c. Subjecting animals to condit stress?	ioning or environmental Yes () No
If yes, describe method and duration of exposure		



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Section 10 - Surgical Procedures

Complete this section if surgical procedures will be performed on live animals. By providing this information, you are justifying the use of the animal model you have selected, supporting your justification for the use of animals for your project and ensuring that no alternatives exist to procedures that cause pain or distress and that these studies have not been previously conducted. The information is to include: the databases searched (2 or more), the date of the search and years covered by the search, and the key words or search strategy used.

a. Are surgical procedures inclu	ded in this protocol?	⊜Yes ⊝No	
b. If yes, please indicate whether the surgical procedure is non-survival (animals will not recover from anesthesia) or survival (animals will recover from anesthesia)		☐ Non-Survival	Number of animals:
c. Multiple survival surgery?		⊖Yes ⊝No	
If yes, justify the multiple surgeries based on scientific necessity. Indicate the specific surgical procedure and the time interval between the procedures.			
d. Briefly describe the surgical procedure(s)			
e. Briefly describe the post- operative care (e.g., length of recovery time following anesthesia).			
f. Where will the surgery be performed (Building/Room Number)?			



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Section 11 - Hazardous Materials

Complete this section if any hazardous materials will be introduced into live animals.

When using hazardous materials in the laboratory, but not with live animals (e.g., formalin fixative) ensure that appropriate SOPs are in place to minimize risk of exposure. For information on SOPs, please contact WSU Environmental Health and Safety (EHS). For a list of Select Agents please refer to the following website: http://www.selectagents.gov/selectagentsandToxinslist.html. For further chemical safety inquiries please contact WSU Chemical Hygiene Office Jamie Herrick at iherrick@westfield.ma.edu.

a. Will hazardous materials be introduced into live animals? Yes No						
b. If yes, what materials will be used with live animals?		☐ Infectious age ☐ Human or non	Radioactive materials Chemicals/carcinogens Infectious agents rDNA (e.g., plasmids) Human or nonhuman primate tissues or cell lines Adjuvants (Freund's or Titer Max Gold)			
 c. If you checked "yes" to infectious agents, rDNA, or human or nonhuman primate materials, Environmental Health and Safety approval is required. 		IBC Approval Number or Reviev Status (e.g., pendi approved)				
d. If you checked "yes" to an	y material above, describe:					
Number of Animals	Agent	Dose per Kg Body Weight	Route of Administration	Frequency of Administration		
e. List the specific health risks to humans and animals from possible exposure to these agents and precautions to be taken to protect people and animals.						



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Section 12 - Aquatic Species

Complete this section when aquatic species (fish, amphibians, and aquatic reptiles) are to be used.				
a. Provide details of tank(s) or enclosures and the cleaning schedule:				
b. Describe maintenance of water quality (e.g., filtered, frequency of change, temperature, pH, removal of metabolites).				
c. Describe routine animal care procedures (e.g., feeding schedule, checking for health of animals).				
d. Describe any hazard (biological, chemical or physical) associated with the maintenance and care of aquatic species and emergency procedures pertinent to the safety of aquatic species and personnel who care for them.				



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Section 13- Field Studies and Animal Collection

Complete this section if field studies involving wild animals will be conducted or animals will from collected in the wild. Ensure that permit from appropriate wildlife agency is sent as part of this submission.				
a. Describe method of capture. Describe safety and protective measures for personnel involved.				
b. Describe procedures to ensure the well being of the animals after capture and during transportation to and from research site (if applicable).				
c. Describe SOPs used as part of field study (attach if applicable).				



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Section 14 - Final Disposition

a. What is the final disposition of the animals in this study?	Animals will be returned to the colony, herd, flock or appropriate cohort group Animals will remain in a natural setting (i.e., observational study) Animals will be euthanized Death will be the endpoint (without investigator intervention, as opposed to euthanasia) Other Please list:
	ons if euthanization is the final disposition. Euthanasia must be conducted in accordance with the <u>iuthanasia</u> . Methods not consistent with AVMA Guidelines must be justified scientifically.
b. Indicate method(s) of euth (include agent, dose and r method of administration, building and room locatio euthanasia will occur).	oute/ Include
c. Will the study require necro animal carcasses?	opsyon Yes If yes, describe procedure:
1. Indicate what method be used to ensure the is dead prior to collect tissues or carcass dispo	animal ing
2. Indicate method of dis of the animal carcasse WSU EH&S for more information.	



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Section 15 - Certifications and Endorsements by Principal Investigator

To indicate agreement, check each statement and sign submittal package.

□ I am familiar with and agree to abide by the University's policies and procedures for research involving animals, including the URI Program of Veterinarian Care and the Animal Care SOPs. □ I am familiar with and agree to abide by the <i>Guide for the Care and Use of Laboratory Animals</i> , The USDA Animal Welfare Act Regulations, and the <i>Public Health Service Policy on Humane Care and Use of Laboratory Animals</i> . □ I certify that the activities in this protocol do not unnecessarily duplicate previous experiments. □ I understand that it is my responsibility as the Principal Investigator to ensure that all individuals listed on the protocol have read and understand the procedures described for each species and have received proper training to conduct the described procedures. □ I understand that if I wish to change any procedure or personnel as shown on this protocol, that I will request an IACUC approval by submitting the details of the change(s) as an amendment to the IACUC. □ I acknowledge that I will notify the Attending Veterinarian (413-623-5329), IACUC Chariperson (413-572-8417) and IACUC Event Report Contact (413-572-8390 or 413-262-0590) of any unanticipated outcome, protocol deviation, or adverse events (e.g., any happening not consistent with routine expected outcomes that results in any unexpected animal welfare issues or human health risks) immediately and complete the Event Reporting form within 72 hours. □ I understand that any failure to comply with guidelines and requirements of the IACUC may result in suspension of my studies and notification to the funding agency, the PHS and/or the USDA as mandated bylaw.	арр	the best of my knowledge the information provided in this protocol form is complete and discation accurately and completely reflects the animal research described in my full grant pplicable) and/or used in my laboratory.	
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Signature of Principle Investigator:			
Signature of Principle Investigator:			
	Sianati	ure of Principle Investigator:	Date:

Print the form for your records

Print Form