

IACUC Protocol/Three Year Renewal Form

VERTEBRATE ANIMAL Research

Rev. April 2019

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, Jason Ramsay at jramsay@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
- 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 <u>jherrick@westfield.ma.edu</u> for further information), and the on-line training courses at

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

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

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Protocol/Three Year Renewal Form Rev. April 2019

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
	ng Certificate(s) Uploaded Animal Husbandry Administer anestheisa
e. Project Title	
f. Type of Application ONew Prote	
g. Anticipated Research Start Date	Anticipated Research End Date
Funding	
h. Is this project funded or being O ^{Yes} submitted for possible funding? ONO	If yes, submit an electronic copy of the grant proposal as part of your protocol package If the project is funded, is the O ^{Yes}
Funding Source	project PHS funded?
Grant/Contract Title	
Grant/Contract ID #:	Proposal Submission Date:
Permits i. Will you be conducting any activities for which a permit is required?	
CollaborationCYesj. Does this project involve collaborationCYeswith another institution?CNo	in yes, submit a copy of the coc approximent the of the instant
Use of Animals in Teaching	
use of animals in cNo numbe years an	st instructor, ment, course r and title, and nd semesters will be taught.





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Section 2 - Personnel

List all personnel associated with the project

a.Co-Investigator

Name			Depart	ment [
Email			Phone	Number		
Check all th	e responsibilities that apply:	Training Certificate(s)	Iploaded	Animal	Husbandry	Administeranestheisa
b. Student l	Researcher(s)	Perform surgery	Perform	neuthanasia	Draw b	lood/performinjection
Name			Name			
Email			Email			
Check all th	e responsibilities that apply:	Training Certificate(s)	Iploaded	Animal	Husbandry	Administeranestheisa
		Perform surgery	Perform	neuthanasia	Draw b	olood/perform injection
Will this project be used as a thesis proposal, directed research, independent study or research paper?				⊖ ^{Yes} ⊃No		

c. Other Personnel

		Responsibilities					
Name	Position	Observation only	Animal Husbandry	anestheisa	Drawblood/ perform injection	Perform surgery	Perform euthanasia
Qualifications							
Qualifications						•	
Qualifications							
Qualifications							
Qualifications							
Qualifications							
Qualifications							

If additional staff are working on this protocol, submit a Personnel Attachment as part of your protocol package





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Section 3 - Animal Care and Use

a. Nontechnical description of the project and its potential value. Describe overall purpose, goals, and significance (e.g., importance to the advancement of scientific knowledge, potential benefits for amelioration of disease) of your project. Write in layman's terms and limit your response to the space provided.

b. Describe the rationale for using animals in this research and the appropriateness of the species to be used.

c. If more than 10 individuals of the same speceis are to me used, please justify the number of animals to be used according to accepted statistical principles or other scientific rationale. Power and sample size calculating tools are available at: http://statpages.org/#Power.

d. Activities involving animals must not unnecessarily duplicate previous experiments. Duplication of previous experiments?

OYes If yes, please

∩ No justify





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Section 4 - Experimental Design

a. Describe procedures that will be performed (use scientific terminology if necessary). Provide concise description of the experimental design (including treatment groups and appropriate controls), endpoints of the experiments, and the procedure conducted on the animals. Include lab methods only as pertinent to understanding the animal usage and welfare. Use the additional space provided on the following page if necessary.





4a. Experimental Design cont.





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4b. If submitting a three year renewal - Describe any changes from your protocol's most recent approval (original or last renewal), including any amended information between approvals. This will give the IACUC a full description of how your protocol has changed from the last full board review. **If this is your original protocol submission, skip this question.**





Section 5 - Animal Information

a. Animal Inventory

Common and Species Name/Strain	Source	Animal Use Classification			Total # of Animalsper Year	Total # of Animals For Project (planned for next 3 years)		
		A	В	□ c	D	E		
		A	В	□ c	D	E		
		A	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 CategoryD orE.

- 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, or holding.

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?

⊖^{Yes} ⊖^{No}

- The USDA Animal Welfare Act covers all warm blooded animals except: (1)birds, rats of the genus *Rattus*, and mice of the genus *Mus*, 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 Anesthetics, Analgesics, or Tranquilizers.

Species	Specific Drug(s)	Dose per Kg Body Weight	Route of Administration	Frequency of 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 **EventReporting Form** must be submitted to the IACUC Chari within 72 hours.





and Water Regulation for Laboratory Animals Policy

Section 7 - Animal Husbandry

a.Preferred location of animal (include building and room#):	5	
b.Will your protocol require ar Facility SOPs for feeding and h		g or husbandry conditions that deviate from normal Animal
Sterile cages	Special bedding	Food regulation
U Wire bottom cages	No bedding	Waterregulation
🗌 No enrichment	Social isolation	Special diet
Other		If yes to water or food regulation, refer to IACUC Food

For any condition checked above, please describe (include the length of time required for each condition) and provide a scientific justification:

Maintenance Outside Animal Facility Housing

Complete this section if animals will be maintained in a laboratory or other area not designated for housing of laboratory animals for more than 24 consecutive hours (12 hours for USDA covered species).

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 original animal facility?	⊖ Yes ⊖ 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 reduce the number of animals used (e.g., special statistical designs, sharing animals/specimens with several projects, etc.); refinements that decrease the pain or distress experienced by the animal; and methods that replace 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.

d.lf you have listed animals in Pain Categories D or E, and no alternatives are available, you must explain the basis for this assertion. An electronic literature search constitutes part of the basis for this assertion, please provide search details utilizing two pertinent sources. Remember to not include the word "alternative" when conducting your search.

Databases	Date of Search	Years Covered	Key Words or Search Strategy

Suggested resources for	
literature sources:	e. The literature
Animal Welfare Information	search yielded
Center - Alternatives	the following
and	information
Consideration of Alternatives to	(attach separate
Painful/Distressful	sheet if needed)
Procedures	·

f. If you have listed animals in Pain Categories D or E, and no alternatives are available, please list one or more experts whom the IACUC may contact who are familiar with the experimental procedures you are using and might render an opinion regarding the appropriate use of animals for these studies. Westfield faculty would be appropriate.





Section 9 - Other Procedures

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

a. Blood collection?	⊖Yes ⊖No	lf yes , re	fer to <u>IACUC policy of Blood Collection</u>
Volume of Blood Draw	Frequency and Number of Sa	Imples	Collection Site

b. Restraining animals with mechanical device? \bigcirc

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?	tioning or environmental CYes CNo
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 included 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 ☐ Survival	Number of animals:	

∩Yes ∩No

c. Multiple survival surgery?

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 postoperative 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: <u>http://www.selectagents.gov/selectagentsandToxinslist.html.</u> For further chemical safety inquiries please contact WSU Chemical Hygiene Office Jamie Herrick at <u>jherrick@westfield.ma.edu</u>.

a. Will hazardous materials be introduced into live animals?	⊖Yes ⊖No	
b. If yes, what materials will be used with live animals?		ials Chemicals/carcinogens rDNA (e.g., plasmids) nan primate tissues or cell lines I'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 Review Status (e.g., pending, approved)	

d. If you checked "yes" to any 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.





Section 12 - Aquatic Species

Complete this section when aquatic species (fish, amphibians, and aquatic reptiles) are to be used.

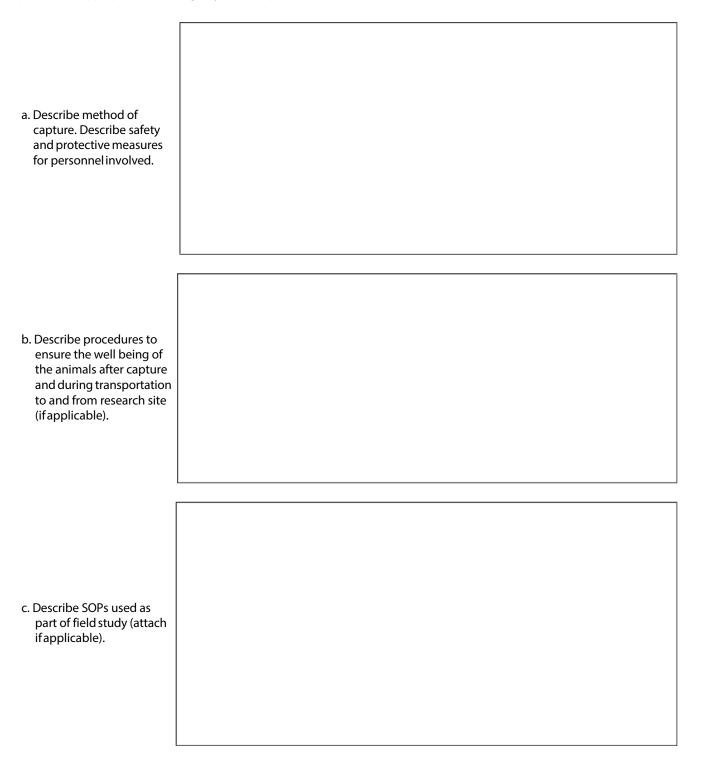
a. Provide details of tank(s) or enclosures and the cleaning schedule:	
b. Describe maintenance of water quality (e.g., filtered, frequency of change, temperature, pH, removal of metabolites).	
c. Describe routine animal care procedures (e.g., feeding schedule, checking for health of animals).	
d. Describe 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.







Section 14 - Final Disposition

a. What is the final disposition of the	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 in this study?	☐ Animals will be euthanized			
	Death will be the endpoint (without investigator intervention, as opposed to euthanasia)			
	Other Please list:			

Complete the following questions if euthanization is the final disposition. Euthanasia must be conducted in accordance with the <u>Report of the AVMA Panel on Euthanasia</u>. Methods not consistent with AVMA Guidelines must be justified scientifically.

b. Indicate method(s) of euthanasia (include agent, dose and route/ method of administration. Include building and room location where euthanasia will occur).			
c. Will the study require necropsy on animal carcasses?	⊖ ^{Yes} ⊖ No	lf yes, describe procedure:	
1. Indicate what method(s) will be used to ensure the animal is dead prior to collecting tissues or carcass disposal.			
2. Indicate method of disposal of the animal carcasses. See <u>WSU EH&S</u> for more information.			





Section 15 - Certifications and Endorsements by Principal Investigator

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

To the best of my knowledge the information provided in this protocol form is complete and accurate and that this application accurately and completely reflects the animal research described in my full grant applications (if applicable) and/or used in my laboratory.
\Box 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> .
\Box 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 413-262-5090) 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 by law.

Signature of Principle Investigator:

Date:

Print the form for your records

PrintForm