

**WESTERN CONNECTICUT STATE UNIVERSITY
Institutional Animal Care and Use Committee (IACUC)
PROTOCOL FOR RESEARCH WITH VERTEBRATE ANIMALS**

Important Notes:

- The IACUC meets in November and May of each year.
- Principal Investigators are encouraged to consult with the IACUC Attending Veterinarian (Dr. Wilson, steven.r.wilson@yale.edu) prior to submitting their protocol.
- Protocols must be submitted by the 10th day of the month preceding a scheduled IACUC meeting (ex. by April 10th for a May meeting). The review of protocols submitted after this deadline may be delayed until the next scheduled IACUC meeting.
- Protocols that involves hazardous materials must obtain the approval of the WCSU Director of Environmental Health and Safety (See “**Concurrences**” section) **prior** to submission
- No faculty, student or staff can acquire vertebrate animals or work with vertebrate animals, for the purposes of teaching or research, without an approved IACUC protocol.
- The work described in the protocol cannot be modified without prior IACUC approval.
- Multi-year protocols must be reviewed and renewed annually.
- Filled forms must be submitted electronically to the IACUC Chairperson (boilyp@wcsu.edu). If approved by the IACUC, the Principal Investigator will be asked to sign the certifications found near the end of this document, and a mail hardcopy to the IACUC Chairperson (P. Boily, Biology, WCSU).

1. Administrative data:

Principal Investigator:

Faculty supervisor (if PI is a student):

Department:

Telephone-Office:

Telephone-Mobile:

E-Mail:

Project Title (course name and number, for teaching projects):

Proposed Project Start Date:

Project End Date:

Funding source:

2. Animal requirements (Provide a copy of the standard operating procedures as **Appendix - Section 2**):

Species-Strain	Age	Sex	Source(s):

Number of Animals:

Species	Year 1	Year 2	Year 3	=	TOTAL

Animal Housing and Procedure Location(s).

Species	Housing Locations	Procedures Locations

Special concerns or requirements: List any special housing, equipment, animal care (*e.g.*, special caging, water, feed, or waste disposal, environmental enhancement, *etc.*). Solid-bottom caging, with bedding is recommended for rodents. **Scientific justification is required for single-housing of rodents, or for housing rodents in wire-bottom cages.** (If applicable, enter details in the text box below)

Special concerns or requirements:

Transportation: Yes No.

Transportation of animals must conform to all institutional guidelines/policies and federal regulations. If animals will be transported on public roads or out of state, describe efforts to comply with USDA regulations. If animals will be transported between facilities or buildings, describe the methods and containment to be utilized (If applicable, enter details in the text box below).

Transportation:

3. Project details

A) Project Objectives:

Briefly describe in non-technical terms the aim of the project and how the project may benefit human or animal health, or advance scientific understanding of biological processes or educational objectives (enter details in the text box below).

Project Objectives:

B) Rationale for animal use:

-Explain your rationale for animal use, which must include reasons why non-animal models cannot be used.
-Justify the appropriateness of the species selected.
-Justify the number of animals to be used. Describe how the number of animals to be used was determined. If possible, summarize this information in a table giving 1) the number of different experiments, 2) the number of groups per experiment, and 3) the number of animals per group. Whenever possible, justify the number of animals statistically (enter details in the text box below).

Rationale for animal use:

C) Experimental design and animal procedures:

Describe the experimental design and all animal procedures. This description should allow the IACUC to understand the experimental course of an animal from its entry into the experiment to the endpoint of the project.

- 1) **Animal Identification Methods** (ear tags, tattoos, collar, leg band, cage card, implant, *etc.*)
- 2) **Injections or Inoculations:** substances (infectious agents, adjuvants, *etc.*), dose, sites, volume, route, and schedules).
- 3) **Blood Withdrawals** (volume, frequency, withdrawal sites, and methodology).
- 4) **Surgical Procedures** (minor or major; survival or non-survival. **Details to be entered in section E**)
- 5) **Radiation** (dosage and schedule)
- 6) **Methods of Restraint** (restraint chairs, collars, vests, harnesses, slings, *etc.*)
- 7) **Resultant Effects**, if any, the animals are expected to experience (pain, distress, ascites production *etc.*)
- 8) **Other potential stressors** (food or water deprivation, noxious stimuli, environmental stress, *etc.*) **and** procedures to monitor and minimize distress.
- 9) **Other Procedures** (behavioral studies, tail biopsies, *etc.*)
- 10) **Experimental Endpoint Criteria** (*e.g.*, tumor size, percentage body weight gain or loss, inability to eat or drink, behavioral abnormalities, clinical symptomology, or signs of toxicity) **must** be specified when the administration of tumor cells, biologics, infectious agents, radiation or toxic chemicals are expected to cause significant symptomology or are potentially lethal. List the criteria to be used to determine when euthanasia is to be performed. Death as an endpoint must always be scientifically justified.

Address the above, if they apply to the project, in the text box below:

Experimental design and animal procedures:

D) Record keeping

Records should include animal or group identification, type of procedure (blood collection: amount, method), type of surgery, euthanasia method, administration of drugs (name, dose, route), *etc.* Initials of personnel, date, and observations relating to animal health and welfare. Describe your record keeping methods in the text box below.

Record keeping methods (Attach your records templates as **Appendix 3D**)

E) Surgery details (survival on non-survival): (Attach detailed response as **Appendix 3E**).

- 1) Minor Surgery (needle aspirations, tail biopsies, *etc.*).
- 2) Major Surgery (entering a body cavity or producing substantial impairment of physical or physiologic functions (such as laparotomy, thoracotomy, craniotomy, joint replacement, or limb amputation).

NOTE: All researchers who perform major surgeries are required to have their surgical procedures observed and approved by the WCSU Attending Veterinarian before performing surgeries independently

- i) Identify and describe the surgical procedure(s) to be performed. Include preoperative procedures (fasting, analgesic loading, *etc.*), and anesthetic monitoring (corneal and pedal reflexes, heart and respiratory rates, *etc.*), and supportive care (ophthalmic ointment, methods to prevent dehydration and hypothermia, *etc.*) during surgery. Include the aseptic methods (animal and human preparations, sterile instruments and field, *etc.*) to be utilized. Provide assurance that antinociception occurs before surgeries begins.
- ii) Who will perform surgery and what are their qualifications and/or experience?
- iii) Where will surgery be performed (Building and Room)?
- iv) Are paralytic agents used during surgery? If yes, please describe how ventilation will be maintained and how pain will be assessed.
- v) If survival surgery, describe post-operative care required, including location, frequency of observation, consideration of the use of post-operative analgesics, and identify the responsible individual(s), and duration of survival after surgery. What impairment can be expected from the surgery and describe any post-operative complications that may develop and your plans to handle them
- vi) Has major survival surgery been performed on any animal prior to being placed on this project?
- vii) Will more than one major survival surgery be performed on an animal while on this project?

Address the above, if they apply to the project, in the text box below:

Surgery details

F) Pain or distress category and consideration of alternatives

Species (common name)	Category* A, B, C or D	Number of animals used each year			3-year total number of animals
		Year 1	Year 2	Year 3	
Total number of animals (should equal total from Section 2):					

Category A: Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes.

Examples: Breeding colonies (includes parents and offspring). Animals held under proper captive conditions or wild animals that are being observed.

Category B: Animals upon which teaching, research, experiments, or tests will be conducted involving no pain, distress, or use of pain-relieving drugs.

Examples: Administration of fluids, administration of oral medication, blood collection from a common peripheral vein per standard veterinary practice or catheterization of same, standard radiography, parenteral injections of non-irritating substances, restrictions of food/water intake for less than equivalent to periods of abstinence in nature. Euthanasia performed following the recommendations of the most recent AVMA Panel on Euthanasia. Manual restraint that is no longer than would be required for a simple exam.

Category C: Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will be used.

Examples: Surgical procedures conducted by trained personnel in accordance with standard veterinary practice such as biopsies, gonadectomy, implantations. Blood collection by more invasive routes such as intracardiac or periorbital collection from species without a true orbital sinus such as rats and guinea pigs. Administration of drugs, chemicals, toxins, or organisms that would be expected to produce pain or distress but which will be alleviated by analgesics.

Category D: Animals upon which teaching, experiments, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs will adversely affect the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests.

Examples: Procedures producing pain or distress unrelieved by analgesics such as toxicity studies, microbial virulence testing, radiation sickness, and research on stress or pain. Surgical and postsurgical sequella from invasion of body cavities, orthopedic procedures, dentistry or other hard or soft tissue damage that produces unrelieved pain or distress. Negative conditioning via electric shocks that would cause pain in humans.

Note Regarding Category D: An explanation of the procedures producing pain or distress in these animals and the justification for not using anesthetic, analgesic or tranquilizing drugs must be provided in the text box below. For USDA (Animal Welfare Act) AWA-covered animals, this information is required to be reported to the USDA, will be available from USDA under the Freedom of Information Act.

Category D justification/explanation

G) Consideration of Alternatives.

The principal investigator must provide written assurance that the proposed activities do not unnecessarily duplicate previous experiments, **and** that no alternative could be found for procedures that cause more than momentary pain or distress (pain categories C or D). Alternatives include methods that (1) refine existing tests by minimizing animal distress, (2) reduce the number of animals necessary for an experiment, or (3) replace whole-animal use with in vitro or other tests, or the use of invertebrate species.

This narrative should include adequate information for the IACUC to assess that a reasonable and good faith effort was made to determine the availability of alternatives or alternative methods. Describe the methods and sources used in the search: the database used (2 or more), the date of the search (must be less than 3 months prior to the protocol submission), the time period covered by the search, and the keywords used. If the database search or other source identifies a bonafide alternative method (one that could be used to accomplish the goals of the animal use proposal), the written narrative should justify why this alternative was not used.

Address the above in the text box below:

Consideration for alternatives

H) Anesthesia, analgesia, tranquilization:

For animals indicated in Section F, Category C or D, specify the anesthetics, analgesics, sedatives or tranquilizers that are to be used. Include the name of the agent(s), the dosage, route and frequency of administration. Describe tracking and security of controlled substances (DEA requirements).

Address the above in the text box below:

Anesthesia, analgesia, tranquilization

I) Method of euthanasia or disposition of animals at end of project

What will happen to the animals at the conclusion of the experiment or demonstration? Techniques for euthanasia must follow the guidelines established by the latest report by the AVMA Panel on Euthanasia. Deviations must be justified for scientific reasons and approved by the IACUC. If euthanasia will be used, provide details: the proposed method, and if a chemical agent is used, specify the dosage and route of administration.

- Anesthetic injection overdose (state drug/dose per body weight/route of administration of drug).
- Exsanguination under anesthesia (state name/dose (per body weight)/route of administration).
- Inhalation of carbon dioxide from a compressed gas cylinder.
- Cervical dislocation
- Decapitation
- Other. Describe: _____

Note: In some animals exposed to gas, heartbeat can be maintained after visible respiration has ceased, and the animal might eventually recover. A thoracotomy or other physical method is recommended to assure death of animals after gas exposure. At minimum, check for both respiratory and cardiac arrest prior to discarding the carcass.

Address the above in the text box below:

Euthanasia details:

J) Hazardous agents in animals

Use of hazardous agents requires the approval of the institutional biosafety specialist. Registration documents for the use of recombinant DNA or potential human pathogens may be required at the discretion of the IACUC.

	YES	NO	List Agents & Registration Document # (if applicable)
Radionuclides			
Biological Agents			
Hazardous Chemicals or Drugs			
Recombinant DNA			

Project conducted at Biosafety Level:

Describe the practices and procedures required for the safe handling and disposal of contaminated animals and material associated with this project. Also describe methods for removal of radioactive waste and, if applicable, the monitoring of radioactivity, and additional safety considerations.

Address the above in the text box below:

Hazardous agents details:

K) **Biological material/animal products for use in animals (cell lines, antiserum, etc.):** ___ Yes ___ No
Specify Material: _____

Source : _____ Material Sterile or Attenuated ___ Yes ___ No

If derived from rodents, has the material been MAP/RAP/HAP tested?
___ Yes (Attach copy of results) ___ No

I certify that the MAP/RAP/HAP tested materials to be used have not been passed through rodent species outside of the animal facility in question and/or the material is derived from the original MAP tested sample. To the best of my knowledge the material remains uncontaminated with rodent pathogens.

_____ Initials of Principal Investigator/Project Director.

L) **Transgenic and knockout animals:** Describe any phenotypic consequences of the genetic manipulations to the animals. Describe any special care or monitoring that the animals will require.

If applicable, address the above in the text box below:

Transgenic/knockout details:

M) **Field studies and wild caught animals:** If animals in the wild will be used, describe how they will be observed, any interactions with the animals, whether the animals will be disturbed or affected, and any special procedures anticipated. Indicate if Federal and/or state permits are required and whether they have been obtained.

If applicable, address the above in the text box below:

Field studies/wild caught animals details:

N) Personnel:

List the name(s), title(s) and qualifications for each research person working with animals, and the procedures to be performed by each. Include the number of years of experience working with the species listed in Section 2. If the person needs to be trained, indicate who will do the training.

Last Name	First Name	Title	Procedures

All live animal work conducted under teaching/classroom projects must be supervised at all times by University faculty or staff listed above. It is the Principle Investigator's responsibility to assure that all participants are properly trained in animal handling and the procedures conducted as part of this project. Keep a list of all such participants with the protocol.

Principle Investigator Certifications:

1. I certify that all personnel involved in this project, including myself, will have completed within the last three (3) years the following www.citiprogram.org modules before starting to work with animals:

List of www.citiprogram.org modules to be completed:

2. I certify that no animal will be acquired prior to the approval of this protocol by the WCSU IACUC, and that the number and species of animals used cannot deviate from what is described in this protocol without prior approval of the WCSU IACUC.
3. I certify that all individuals working on this project will complete any required WCSU Occupational Health and Safety Program before starting to work with animals.
4. I certify that I have read the WCSU IACUC Whistleblower Policy and of the WCSU IACUC Disaster Plan, and that I will provide copies of these documents to all personnel involved in this project.
5. I certify that I will obtain approval from the IACUC before initiating any significant changes in this project.
6. For multi-year protocols, I certify that I will submit an annual continuation form one month prior to each anniversary of the approval of the protocol.
7. I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research.
8. For all Category C and Category D projects (see Section J): I certify that I have reviewed the pertinent scientific literature and have found no valid alternative to any procedures described herein which may cause more than momentary pain or distress, whether it is relieved or not.
9. I certify that I will notify the IACUC regarding any unexpected project results that impact the animals. Any unanticipated pain or distress, morbidity or mortality will be reported immediately to the attending veterinarian and the IACUC.
10. I certify that copies of the approved protocol will be made available to all laboratory personnel.
11. I certify that I shall monitor drugs used in my laboratory and shall insure that outdated drugs are promptly discarded according to applicable local, state and federal regulations.
12. I certify that I shall maintain complete, up-to-date, and accessible records of procedures for the animals used in this project, for the whole duration of the project and for three (3) years after its completion.
13. I will comply with the procedures described in the *Guide for the Care and Use of Laboratory Animals* (National Academy of Sciences, 2011), with PHS Policy, the Animal Welfare Act, and applicable University policies.

Principal investigator's/Project Director's Signature

Date

If this is a student research project, the supervising faculty member must also sign to certify that all of the above procedures will be followed.

Supervising Faculty Member

Date

Concurrences:

1. For all projects housing animals at WCSU:

Animal Facility Supervisor certification that the necessary physical and human resources are available to support the proposed project.

Attach a copy on an email (**As Appendix - Concurrence 1**) confirming that appropriate housing and procedure facilities, supplies and support staff are available for the proposed work. Email must contain the name, contact information and title of facility supervisor.

2. For all projects that involve Pain and Distress Categories C or D projects (see Section F):

Attending Veterinarian certification of review and concurrence.

Attach a copy on an email (**As Appendix - Concurrence 2**) confirming that the appropriate use of analgesics and anesthetics has been reviewed and discussed with the PI. Email must contain the name, contact information and title of the Attending veterinarian.

3. For all projects using hazardous agents (see Section J):

Director of Environmental Health and Safety Programs certification of review and concurrence.

Attach a copy on an email (**As Appendix - Concurrence 3**) confirming that the use of hazardous agents has been reviewed and discussed with the PI, and that the appropriate safety measures are in place. Email must contain the name, contact information and title of Health and Safety representative.

Final Approval:

Once approved, the IACUC Chair will send an approval email to the PI that specifies the protocol number, project title, date of approval, and date of expiration.

Appendices
Documents provided to PIs when they submit a protocol

WCSU-IACUC Animal Disaster Plan

WCSU-IACUC Whistleblower Policy

WCSU-IACUC Animal Disaster Plan

Critical Incident Response Team (CRIT)

Name	Title	Role in CRIT	Contact Information
Dr Steven Wilson	Attending Veterinarian	Consultation	203-785-6067 Work 860-304-2063 Cell
Dr Pat Boily	IACUC Chair and PI	Team Leader (1)	203-837-8569 Work 475-529-5795 Cell
Dr Josh Cordeira	PI	Alternate Team Leader (2)	203-837-8940 Work 508-789-6621 Cell
Dr. Michelle Monette	IACUC member and PI	Alternate Team Leader (3)	203-837-9894 Work 617-584-2724 Cell
Dr. Neeta Connally	IACUC member	Alternate Team Leader (4)	203-837-8749 Work 914-582-7224 Cell
Mr. Pano Koukopoulos	Director Environmental Health & Safety Programs	Support	203-837-9352 Work 203-460-6629 Cell
Dr Michelle Brown	Dean, Arts and Sciences	Administrative	203-837-9401 Work
Dr Mary Alexander	Provost	Institutional Official (IO)	203-837-8400 Work
Mr. Richard Guerrera	Chief of Police, WCSU	Security and safety	203-837-9301 Office 203-837-9300 (dispatch) 911 (emergency)

General:

- 1- This Plan should be distributed to all CRIT members and all PIs who have animals covered by a WCSU IACUC protocol
- 2- If the Team Leader is unable to perform his or her duties, then the Alternate Team Leader identified with the next number under the "Role" column shall become the new Team Leader. If necessary, the Provost has the power to appoint a Team Leader not listed in the above table.
- 3- In the event of an incident that is likely to endanger the welfare or lives of animals covered by a WCSU IACUC protocol, the Team Leader will make every reasonable attempt to contact and consult with the Veterinarian and the PI responsible for the animals before taking any action. However, the Team Leader has the authority to take necessary actions if such contacts cannot be established within a reasonable amount of time.
- 4- The Team Leader will have access to the animal facility at all times unless the University Police determines that this would endanger the safety of the staff.
- 5- All CRIT members will be contacted for debriefing within 24 hours of an emergency response.

PROCEDURES

- 1- Level 1 incident. Predictable, short-term events (<24hrs) that may affect the health and welfare of animals covered by a WCSU IACUC protocol. Such incidents include but are not limited to: weather events (ex. snow storms), maintenance procedures that may affect or limit access to the animal care facilities.
 - a. In preparation for the event (ex. forecasted snow storm), the PI must insure that animals are provided with enough food and clean water to last for at least 2 days.
 - b. Within 24hrs, the PI must inspect the facilities, and make sure that proper environmental conditions are restored (temperature, humidity, photoperiod), and request corrective measures if necessary.
 - c. The event must be documented by the PI in the animal care logs
- 2- Level 2 incident. Severe weather or unpredictable events that may affect the health and welfare of animals covered by a WCSU IACUC protocol for less than 48hrs. Such incidents include but are not limited to: severe weather events (ex. major snow storm) and unexpected power or HVAC failures.
 - a. If the event is predictable (ex. forecasted major snow storm), then the PI must insure that animals are provided with enough food and clean water to last for at least four (4) days. Animal enclosures (cages, tanks, etc.) must be cleaned in preparation of the event.
 - b. Within 48hrs, the PI must inspect the facilities, and make sure that proper environmental conditions are restored (temperature, humidity, photoperiod), and request corrective measures if necessary.
 - c. The event must be documented by the PI in the animal care logs
- 3- Level 3 incident. Disaster or emergency that do not cause an immediate danger to the health or lives of animals covered by a WCSU IACUC protocol, but that can affect their welfare in the long term. Such incidents include but are not limited to prolonged power or HVAC failures, minor fires, insect or mold infestation.
 - a. If the animal care facilities are disabled to the point that they can no longer safely house the animals, and that the animals can be safely moved to an alternative facility, then the Team Leader will coordinate the move of the affected animals. Moving the animals will be performed as soon as possible without endangering the health and safety of the staff or of the animals.
 - b. If the animal care facilities are partially disabled but still acceptable to hold animals if temporary corrective measure are taken, then the Team Leader will, with consultation with the Attending Veterinarian and the PI, coordinate the corrective measures to ensure the proper welfare of the animals.
 - c. The event must be documented by the Team Leader or the PI in the animal care logs, and reported to all IACUC members and to the IO.
- 4- Level 4 incident. Disaster or emergency that cause an immediate danger the health or lives of animals covered by a WCSU IACUC protocol. Such incidents include but are not limited to substantial building damage caused by a fire or a natural disaster.
 - a. If the incident is judged by the Team Leader to be severe enough that the animals will inevitably suffer severe pain and distress, the affected animals will be euthanized (following AVMA guidelines) by the Team Leader or by another qualified CRIT member designated by the Team Leader. Euthanasia will be performed as soon as possible without endangering the health and safety of the staff. A good faith effort will be made to contact the PI prior to euthanizing the animals.
 - b. If the animal care facilities are disabled to the point that they can no longer safely house the animals and that the animals cannot be safely moved to another facility, the affected animals

will be euthanized (following AVMA guidelines) by the Team Leader or by another qualified CRIT member designated by the Team Leader. Euthanasia will be performed as soon as possible without endangering the health and safety of the staff. A good faith effort will be made to contact the PI prior to euthanizing the animals.

- c. The event must be documented by the Team Leader or the PI in the animal care logs, and reported to all IACUC members and to the IO.

Adopted by the WCSU IACUC January 2019

How to Report Animal Welfare Concerns

WCSU is committed to the humane care and use of animals involved in research and teaching. WCSU expects all faculty, staff and students to work with animals ethically, and to comply with applicable federal, state and local laws and regulations, and WCSU policies and procedures. WCSU's Institutional Animal Care and Use Committee (IACUC) is required to investigate reports of suspected abuse or mistreatment of animals used in teaching or research at WCSU. You should report any observed or suspected animal abuse, mistreatment, or non-compliance with federal, state, or local regulations, or non-compliance with an approved protocol.

The Federal Animal Welfare Act prohibits the discrimination or reprisal against any person reporting a violation of animal welfare regulations or standards. WCSU's whistleblower policy also prohibits discrimination or retaliation against individuals who report concerns regarding unethical practices or violation of State or Federal laws or regulations. (https://www.wcsu.edu/hr/policies-procedures/Whistleblower_Policy.pdf)

Animal Welfare concerns can be reported to anyone on this list:

Title	Contact	Phone	E-mail
IACUC Attending Veterinarian	Dr. S. Wilson	203-785-6067	steven.r.wilson@yale.edu
Professor- Biology, IACUC Chair	Dr. P. Boily	203-837-8569	boilyp@wcsu.edu
Director-Sponsored Research, Adm. Services, IACUC Member	G. Jazwiecki	203-837-8281	jazwieckig@wcsu.edu
Associate Professor-Biology, IACUC Member	Dr. M. Monette	203-837-9894	monettem@wcsu.edu
Associate Professor- Biology, Alternate IACUC Member	Dr. N. Connally	203-837-8749	Connallyn@wcsu.edu
Dean Macricostas School of Arts and Sciences	Dr. M. Brown	203-837-9400	brownml@wcsu.edu
Provost/Vice-President of Academic Affairs (IO)	Dr. M Alexander	203-837-8400	alexanderm@wcsu.edu

It is helpful if you provide your name and contact information in case the IACUC has further questions. However, you can report your concerns anonymously. Your report, made anonymously or not, will be dealt with confidentially to the extent reasonably possible.

WCSU-IACUC Whistleblower Policy

Policy about Reporting Animal Care and Use Concerns

Background

WCSU is committed to the humane care and use of animals involved in research and teaching. WCSU takes seriously its responsibility to ensure that animals are always treated humanely.

WCSU expects all faculty, staff and students to conduct research ethically and to comply with applicable federal, state and local laws and regulations, and WCSU policies and procedures.

This policy statement is compatible with the "WCSU Whistleblower policy":
https://www.wcsu.edu/hr/policies-procedures/Whistleblower_Policy.pdf

Applicable Regulations

(Based on the Animal Welfare Act 9 CFR 2.31 and Public Health Service Policy IV.B)

WCSU's Institutional Animal Care and Use Committee (IACUC) is required to investigate reports of suspected abuse or mistreatment of animals used in teaching or research at WCSU.

Training and instruction of all faculty, staff and students who work with animals shall inform how deficiencies in animal care and use can be reported.

No WCSU employee, IACUC member, laboratory personnel or student shall be discriminated against or subject to any reprisal for reporting violations of any animal care and use regulation or standards.

Policy Statement

Any individual having a concern about the care and/or use of laboratory animals at WCSU should report that concern. The concern will be investigated appropriately and, if requested, the concerned individual will be notified of the progress or outcome of the investigation.

- WCSU ensures that no individual shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standard pertaining to animals used for teaching or research.
- A concern or report can be made anonymously. Whether or not made anonymously, all reviews and investigations will be dealt with confidentially to the extent reasonably possible.

Guidance for Individuals with Concerns

- Any individual with concerns regarding animal care and use, animal handlers, adherence to approved protocols, or related matters can bring their concerns to the attention of WCSU by contacting any of the individuals or offices listed on the signage attached to this policy document.
- If the individual is not sure a situation warrants official reporting, he/she is encouraged to seek guidance and additional information about the situation from any WCSU representative listed on the signage attached to this policy document.

Guidance for Individuals Receiving Concerns

- When a WCSU representative is contacted by an individual wishing to make informal or anonymous inquiries, the discussion should begin with the representative clearly disclosing the following:
 - The individual has the option of stopping the discussion and reporting their concerns themselves at any point via appropriate official channels.
 - If in the course of discussion, the individual determines the matter should be reported, if requested to do so by the individual, the WCSU representative can make the report on behalf of the individual to maintain the individual's anonymity.
 - If the WCSU representative determines that the matter should be reported, but the individual disagrees, the representative is required to inform the Institutional Official (IO) and the IACUC of the matter, without disclosing the individual's identity.

Procedure to follow when animal welfare concerns are reported to the IACUC

The recipient of a report about an animal welfare concern must notify the IACUC Chair and the IO as soon as possible. If the IACUC Chair is directly or indirectly associated with the reported concern, the IO will appoint an interim-Chair to coordinate the process.

1. Initial Steps:

- If the reported activity, situation and/or condition is occurring and potentially involves an imminent animal welfare concern, the IACUC Chair/Interim-Chair will request that the Attending Veterinarian initiate an immediate on-site assessment of the animal(s) and/or condition(s) and address any animal welfare issues under their authority.
- If the reported activity, situation and/or condition is either not currently occurring or does not potentially involve an imminent animal welfare concern, the IACUC Chair/Interim-Chair will notify the Institutional Official (IO) and all IACUC members of the reported concern. If any of these individuals are associated with the concern, they will not be notified at this point.

2. IACUC Notification:

- The IACUC must consider all allegations of noncompliance, animal care and use, and animal welfare, and determine if there is sufficient reason to warrant further investigation based on regulatory requirements.
- If the nature of the reported concern is such that the IACUC should discuss the situation before the next scheduled convened meeting, the Chair/IACUC-Chair will call for a committee meeting to discuss the reported concern; business will not be conducted unless a quorum is present.
- If notification prior to the next convened IACUC meeting is not required, the Chair/Interim-Chair will report on the reported concern and review and/or investigation process initiated at the next convened IACUC meeting. The IACUC can either accept the plan initiated or request a

modification to the plan. The Chair/Interim-Chair will oversee any IACUC requested changes to the plan.

3. Review/Investigation Team:

- The Chair/Interim-Chair, in consultation with the IO, will form a subcommittee to review and investigate the reported concern. Under most circumstance, the subcommittee will be composed of Chair/Interim-Chair, the Attending Veterinarian, plus one IACUC member. If additional expertise is required, additional individuals may be added to the subcommittee to assist in conducting the review and/or investigation.

4. Outcome of Review/Investigation:

- Following completion of the review/ investigative process, a report will be presented to the full IACUC at a convened meeting. The report will also be provided to the IO, who will be invited to attend the meeting. The report should include:
 - An executive summary
 - Members of the review/investigative group
 - A description of activities conducted as part of the review/investigation
 - Findings from the review/investigation
 - Conclusions from the review/investigation
 - Recommendations for addressing the concern and minimizing the chance of re-occurrence

5. IACUC Actions

- IACUC response to the report may include, but are not limited to the following:
 - Acceptance of the report and recommendations
 - Acceptance of the report, but revision of the recommendations
 - Rejection of either the report or recommendations, in which case the IACUC will determine appropriate resolution and/or corrective actions
 - If protocol suspension is included in the IACUC approved resolution or corrective actions to the situation, the IO will be informed, who will immediately inform OLAW.

6. Reportable to Regulatory Agencies

- If the nature of the reported concern is such that OLAW should be immediately notified, the IO will contact OLAW by phone.
- If the review/investigation determines that the reported concern involves non-compliance or an animal welfare issue that is reportable to OLAW, but did not require an immediate notification the IO will send an email to OLAW with the initial report.
- If the outcome of the review/investigation results in IACUC suspension of an approved activity, the IO will immediately inform OLAW.

7. Records of the Reported Concern

- The IACUC Chair/Interim-Chair will ensure that all documents related to the reported concern are retained in a location dedicated to such reports for the required retention period.
- The IACUC Chair/Interim-Chair will ensure that an up-to-date list of activities related to the review and/or investigation is maintained and that it includes the date, description of the activity and status of the process. This information will be retained for the required retention period.
- Official reports will have personal information redacted while maintaining the details supporting the report.

- If the individual that reported the concern wishes to be notified of the outcome of the review/investigation and/or the recommendations of the reviewing/investigating body/IACUC, the IACUC Chair/Interim-Chair will work with University Officials to draft a response to the reporting individual.

Training

- Training shall be made available on how deficiencies in animal care and use can be reported by any individual.
 - To comply, a section about reporting animal care and use concerns is included in the IACUC on-line training course (“Citi Program”) taken by all faculty, staff and students who work with animals used for teaching or research.
- Reporting instructions will be posted in prominent, appropriate locations within the institution.

Adopted by the IACUC, January 2019