



Office of Animal Care Compliance

April 4, 2019

[REDACTED]
Executive Vice Chancellor
Vice Chancellor for Research
[REDACTED]

RE: Spring 2019 [REDACTED] Semi-Annual Animal Care and Use Program Review, PI Laboratory and Animal Resource Facility Inspections

Mandated by the US Public Health Service, Office of Laboratory Animal Welfare (OLAW) and the Animal Welfare Act and Animal Welfare Regulations (AWAR and AWAR), the semi-annual inspections of the [REDACTED] Animal Resource Facilities (ARF) and PI laboratories were conducted from March 4th through the 15th, 2019. The [REDACTED] Institutional Animal Care and Use Committee (IACUC) inspectors included:

[REDACTED] (Community Member) [REDACTED] (Attending Veterinarian), Dr. [REDACTED] and Dr. [REDACTED]

[REDACTED] The Office of Animal Care Compliance (OACC) Sr. Operations Manager, [REDACTED], and the OACC Compliance Specialist, [REDACTED] were included on the inspection team. The inspectors were escorted in the ARF by ARF Supervisor, [REDACTED] in the ARF [REDACTED] by [REDACTED] and in [REDACTED] by [REDACTED] and Dr. [REDACTED]

The semi-annual program review was completed at the convened [REDACTED] IACUC meeting on April 4, 2019. The program continues to adhere to provisions of the Guide for the Care and Use of Laboratory Animals, Eighth Edition, the Public Health Service Policy on Humane Care and Use of Laboratory Animals, IV.B. 1-8, and the Animal Welfare Act and Regulations, title 9, chapter 1, subchapter A.

Overall adherence to approved protocols by principal investigators was found to be excellent. The Animal Facility was found to be exceptionally well organized, neat, and clean. [REDACTED] continues to manage a well-trained team of technicians displaying dedication and high standards of animal care. There are still five chemical fume hoods in PI laboratories where animals, their blood/cells, or tissues are handled that are marked as "Do Not Use" because they have not yet been recertified since the contractor placed in line dampers in the ducts to control air flow. This issue should be resolved in May during the regularly scheduled hood certification.



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Attached to this letter is a detailed summary of inspection findings. These findings are specified as: A= acceptable, M = minor deficiencies, S = significant deficiencies (are or may be a threat to animal health or safety), C= Change in program, and N/A=not applicable.

There were no dissenting or minority views expressed during the past six months.

If you would like to discuss any of these findings or comments, please feel free to contact me at any time. We thank you for your continued support of the IACUC and the animal research facilities as well as the investigators whose research programs are dependent on the use of animals.

Sincerely,

A large black rectangular box redacting the signature of the IACUC Chair.

IACUC Chair

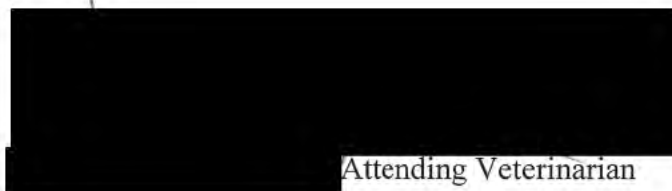
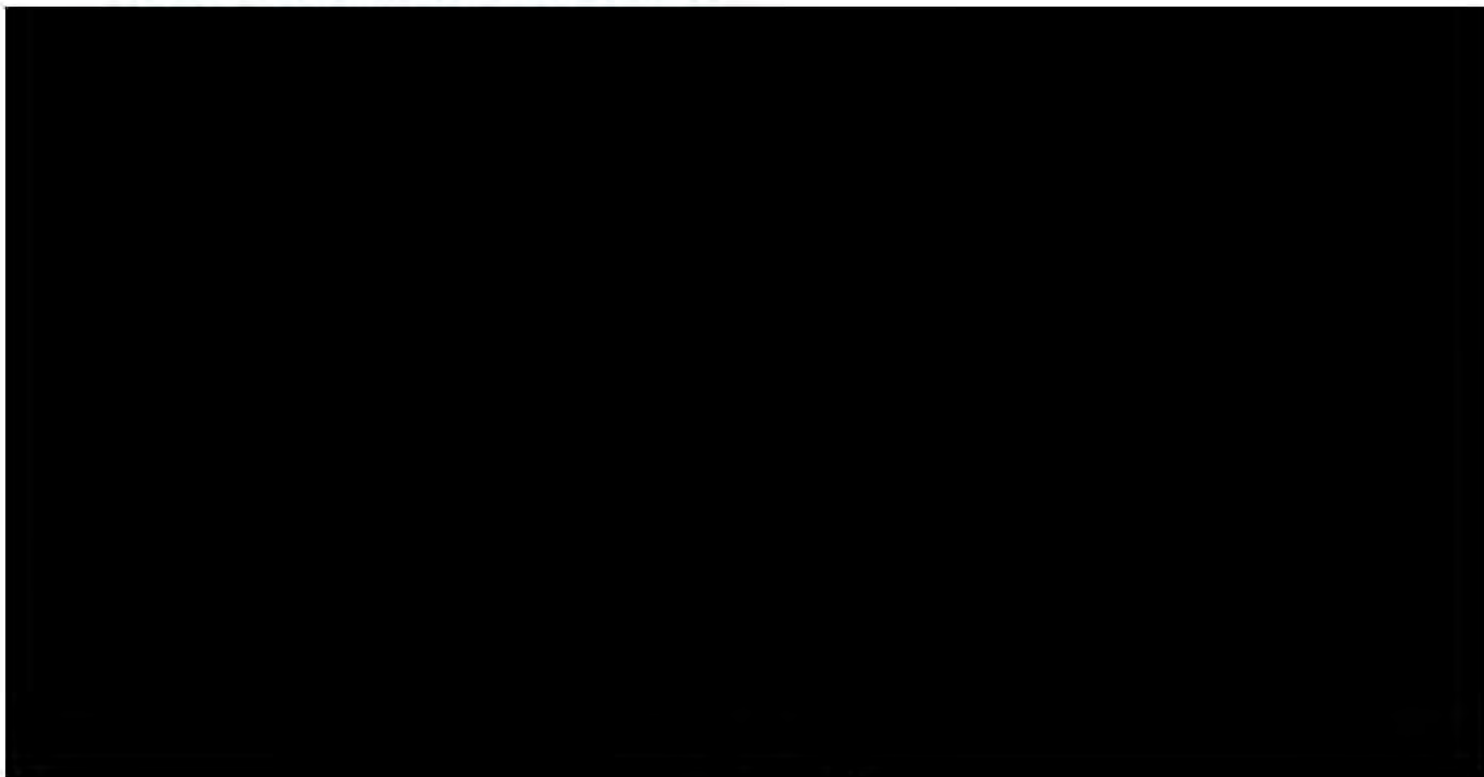
4/4/2019
Date



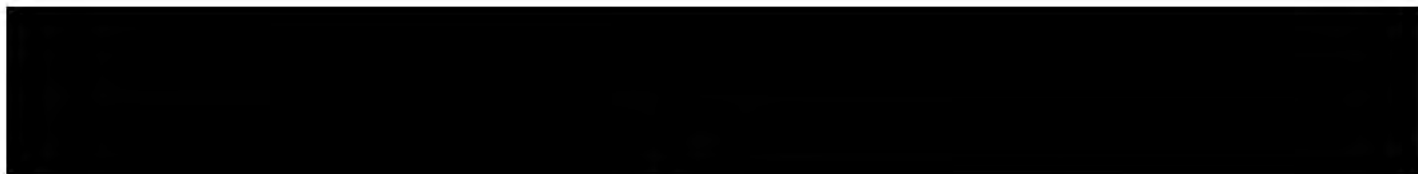


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Office of Animal Care Compliance



Attending Veterinarian





Date

4/4/19



Office of Animal Care Compliance

Exception - Multiple Species Housing within Room

There is only one animal room each in the  bio-containment facility located in the  and the current biohazard research program requires use of both mice and rat species at each biohazard risk level. For this reason, we need to house mice and rats in the same rooms. However, each species is segregated in separate ventilated cage/racks systems. Also, each room has approximately 15 fresh air changes per hour with no air recirculation. Supply air for each rack is drawn from the room through a High Efficiency Particulate Air (HEPA) filter and distributed to each cage. Subsequently all air from the cages is HEPA filtered and exhausted directly out of the building through the building exhaust ducting. In addition, procedures with mice and rats are not conducted at the same time and generally all procedures are conducted inside a BSC. The aforementioned building mechanical system, ventilated rack design, and methods significantly minimize the stress to animals that can be associated with exposure to interspecies odors or close proximity.

Semi-annual IACUC Review – April 4, 2019

Semi-annual Inspection of Laboratories and Animal Facilities
March 4 thru 15, 2019

Inspectors	Deficiencies A,M,S,C, NA	Location and Lab Function	Deficiency and Plan for Correction and Action (if any)	Responsible Party	Correction Schedule	Date Completed
	A		Neat and clean. No deficiencies noted.	ARF	N/A	N/A
	A		Exceptionally neat and clean. No deficiencies noted.	ARF/ Multiple	N/A	N/A
	A		Neat and clean. No deficiencies noted.	ARF	N/A	N/A
	A		Neat and clean. No deficiencies noted. Note: Five rabbits are currently being housed in quarantine.	ARF	N/A	N/A
	M		Neat and clean. 1) Daily checkmarks for feed, water, etc. are not being filled in by PI lab while under their caring – rather they were placing post-it notes. Lab staff should be trained to enter data directly to the room log.	ARF	Correct by 3/29/19.	Corrected on 3/21/19.
	M		Neat and clean. 1) The eye wash card had not been initialed in the last month so the eye wash was checked and initialed immediately by lab staff. PIs should ensure that the eyewashes are being checked promptly once they reach the due date. ARF should coordinate with the lab members and decide who will be responsible for completion and documentation of the monthly eyewash checks going	ARF/ Multiple	N/A	N/A

			immediately. 3) A full sharps container should be replaced.			
	A		Neat and clean. No deficiencies noted.	ARF	N/A	N/A
	A		Very neat and clean. No deficiencies noted.	ARF	N/A	N/A
	A		Neat and clean. No deficiencies noted.	ARF	N/A	N/A
	A		Neat and clean. No deficiencies noted.	ARF	N/A	N/A
	A		Neat and clean. NO deficiencies noted. The door into the room has some play in the frame but this has been checked out and the door is secure.	ARF/ Multiple	N/A	N/A
	M		Space could be neater overall. 1) Two pairs of clippers in the cabinets had fur in them. Clean after each use. 2) The sink is coated with hard water deposits. Descal the sink. 3) Expired EtOH, pipettes, spinal cord needle set, and sodium chloride were removed from several of the cabinets. Segregate expired materials and mark them as "non-survival procedures only". 4) A cardboard box full of expired Alcohol swab sticks that was being stored out on the shelf was placed behind the class doors. All surfaces in surgical areas must be able to be sanitized.	ARF	Correct by 3/29/19.	Corrected on 3/25/19.
	M		Neat and clean. 1) Expired diabetic testing materials (test strips) were disposed of immediately. 2) Expired Iodine and NTZ buffer were disposed of immediately. 3) Used syringes with needles were found in non-puncture proof box rather than a sharps container. Train staff to dispose of sharps and hazards properly.		Correct by 3/29/19	Corrected on 3/26/19.

	M		Neat and clean. 1) Expired honey		Correct by 3/29/19.	Corrected on 3/19/19.
	A		Neat and clean. No deficiencies noted.	ARF	N/A	N/A
	A		Neat and clean. No deficiencies noted.	ARF	N/A	N/A
	A		Neat and clean. No deficiencies noted.		N/A	N/A
	A		Neat and clean. No deficiencies noted.	ARF	N/A	N/A
	A		Neat and clean. No deficiencies noted.	ARF	N/A	N/A
	M		Neat and clean. Not in use until floor is repaired. 1) 3 bottles of expired Sodium Chloride were removed immediately from cabinet #8. 2) Two bottles of expired drugs were removed immediately from a PI cabinet. 3) A 3' square section of the Nora flooring was removed during repair of the floor drain and a contractor is scheduled to replace the flooring.	ARF	Correct #2 by 3/29/19	# 2 corrected 3/21/19
	M		Could be neater and cleaner. 1) There was a corncob bedding bin dated from 2016 that		N/A	N/A

		room	2) The floor was dirty so it should be swept and mopped.			
	M		Neat and clean. 1) One stereotaxic platform was dirty and should be cleaned. 2) An unmarked charcoal canister was disposed of immediately.	Multiple	Correct #1 by 3/29/2019	Corrected on 3/29/19
	M		Neat and clean. 1) Several syringes containing heparin were found in the drawers in the surgery area. They should all be labeled with the date they were aliquoted and the drug concentration. 2) An expired bottle of Quatricide disinfectant was found and was disposed of immediately.	Multiple	Correct #1 by 3/29/2019	Corrected on 3/29/19
	M		Neat and clean. 1) There was no plastic liner in the glass disposal box. All glass disposal boxes come with a liner that should be used in order to catch glass shards that may escape the box. Place a liner in the glass disposal box.	Morton/ Multiple	Correct by 3/29/2019	Corrected on 3/29/19
	A		Could be neater and cleaner. Just as a note, there are some storage boxes by the door to the lab that should be cleaned out if they belong to PIs who are no longer working with animals in this space. Any expired materials in those boxes should be disposed of.	Morton	N/A	N/A
	M		Neat and clean. 1) There was an unmarked jar in one of the drawers that contained what appeared to be old, labeled skull caps that was disposed of immediately. 2) Several syringes containing heparin were found in the drawers in the surgery area. They should all be labeled with the date they were aliquoted and the drug concentration. 3) There was a container of expired PBS in the fridge that was disposed of immediately.	Multiple	Correct #2 by 3/29/19	Corrected on 3/29/19
	M		Neat and clean.	Multiple	N/A	N/A

A	Very neat and clean. No deficiencies noted.	N/A	N/A
M	<p>Very neat and clean.</p> <p>1) One empty drug bottle (within date) was found and should be returned to the ARF.</p> <p>2) One sharps container was full to the line and was removed immediately.</p> <p>3) There was some cardboard in the survival surgery area that should be removed.</p> <p>4) Just as a note there was some crust outside the rim of one of the drug bottles. The PI will discuss this with the AV. It was determined that the stopper for that lot of glass vials are defective and ARF replaced with a vial from a new lot. The old vials allowed leakage but should not have affected remaining drug efficacy.</p>	Correct #3 by 3/29/19	Corrected on 3/20/19.
A	Could be neater and cleaner. No deficiencies noted.	N/A	N/A
M	<p>No animals are handled in this area. Drug storage only. 1)</p> <p>1) There was one empty drug bottle in the safe. Empty drug bottles should be returned to the ARF immediately.</p>	N/A	N/A
	PI Animal Use Laboratories		
A	Neat and clean. No deficiencies noted.	N/A	N/A
M	<p>Neat and clean.</p> <p>1) The eye wash card had not been initialed in the last month so the eye wash was checked and initialed immediately by the lab staff. The eyewashes are being checked routinely, they were all just a few days past the monthly due date. PIs should ensure that the eyewashes are being checked promptly once they reach the due date.</p>	N/A	N/A
	PI Animal Use Laboratories		
A	Neat and clean. No deficiencies noted.	N/A	N/A

		only				
	A		Neat and clean. No deficiencies noted.		N/A	N/A
	A		Neat and clean. No deficiencies noted.		N/A	N/A
	M		<p>Neat and clean overall.</p> <p>1) The eye wash card had not been initialed in the last month so the eye wash was checked and initialed immediately by the lab staff. The eyewashes are being checked routinely, they were all just a few days past the monthly due date. PIs should ensure that the eyewashes are being checked promptly once they reach the due date.</p> <p>2) The chemical fume hood is still marked as "Do not use" but is not currently being used for animal work. Animal work requiring the use of a chemical fume hood must be carried out in a certified hood</p>		Correct #2 as funds become available.	Note for item #2: Dampers were installed on all the chemical fume hoods that were not certified and the air flow has been pre-set so that they can pass inspection by [REDACTED] in May.
	M		<p>Neat and clean overall. PI uses downdraft table in the ARF for perfusions because of the non-working hood.</p> <p>1) The chemical fume hood is still marked as "Do not use" but is not currently being used for animal work. Animal work requiring the use of a chemical fume hood must be carried out in a certified hood</p>		Correct as funds become available.	Note for item #2: Dampers were installed on all the chemical fume hoods that were not certified and the air flow has been pre-set so that

						they can pass inspection by [REDACTED] in May.
[REDACTED]	M	[REDACTED]	<p>Neat and clean overall.</p> <p>1) The eye wash card had not been initialed in the last month so the eye wash was checked and initialed immediately by lab staff. The eyewashes are being checked routinely, they were all just a few days past the monthly due date. PIs should ensure that the eyewashes are being checked promptly once they reach the due date.</p>	[REDACTED]	N/A	N/A
[REDACTED]	M	[REDACTED]	<p>Neat and clean overall.</p> <p>1) The eye wash card had not been initialed in the last month so the eye wash was checked and initialed immediately by lab staff. The eyewashes are being checked routinely, they were all just a few days past the monthly due date. PIs should ensure that the eyewashes are being checked promptly once they reach the due date.</p> <p>2) The chemical fume hood is still marked as "Do not use" but is not currently being used for animal work. Animal work requiring the use of a chemical fume hood must be carried out in a certified hood</p>	[REDACTED]	Correct #2 as funds become available.	Note for item #2: Dampers were installed on all the chemical fume hoods that were not certified and the air flow has been pre-set so that they can pass inspection by [REDACTED] in May.
[REDACTED]	M	[REDACTED]	<p>Neat and clean.</p> <p>1) The eye wash card had not been initialed in the last month so the eye wash was checked and initialed immediately by lab staff. The eyewashes are being checked routinely, they were all just a few days past the monthly due date. PIs should ensure that the eyewashes are being checked promptly once they reach the due date.</p> <p>2) An uncapped needle that posed a sharps risk was secured immediately.</p>	[REDACTED]	N/A	N/A

		<p>1) The eye wash card had not been initialed in the last month so the eye wash was checked and initialed immediately by lab staff. The eyewashes are being checked routinely, they were all just a few days past the monthly due date.</p> <p>2) One bottle of expired drug was returned to the ARF immediately.</p>			
	A	Neat and clean. No deficiencies noted.		N/A	N/A
	M	<p>General housekeeping is needed.</p> <p>1) Euthanasia chambers had urine or feces in them. Clean all euthanasia chambers after each use.</p> <p>2) The eye wash card had not been initialed in the last month so the eye wash was checked and initialed immediately by lab staff. The eyewashes are being checked routinely, they were all just a few days past the monthly due date. PIs should ensure that the eyewashes are being checked promptly once they reach the due date.</p> <p>3) Carboy spigots were not placed over secondary containment so can drip on the floor and cause a slip hazard. Place carboy spigots over the sink or secondary containers in order to catch drips.</p>		Correct by 3/29/19	Corrected on 3/25/19.
	A	Neat and clean. No deficiencies noted.		N/A	N/A
	A	Neat and clean. No deficiencies noted.		N/A	N/A

A= acceptable, M = minor deficiencies, S = significant deficiencies (are or may be a threat to animal health or safety), and C= Change in program, N/A=not applicable

Semiannual Program Review and Facility Inspection Checklist

About the checklist

The Semiannual Program Review and Facility Inspection Checklist is provided to assist institutions in conducting their semiannual reviews of programs and facilities for the care and use of animals. The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals ([Policy](#)), section [IV.B.1.-2.](#), requires the Institutional Animal Care and Use Committee (IACUC) to review the institution's program for humane care and use of animals and inspect all of the institution's animal facilities at least once every 6 months using the *Guide for the Care and Use of Laboratory Animals: Eighth Edition* ([Guide](#)) as a basis for evaluation.

How to use the checklist

This checklist is a tool to assist IACUCs in conducting thorough semiannual reviews. IACUCs are not required to use this checklist but are encouraged to amend it as necessary to reflect institutional programs and needs, or to develop their own checklist. If the checklist is modified, periodic review of the checklist is recommended to ensure relevant topics are considered as the animal care and use program changes.

The checklist covers the major topics of the *Guide* and the requirements of the PHS Policy. The checklist does not replace the *Guide*, but should be utilized in conjunction with the *Guide*. The *Guide* provides the standards, recommendations, and descriptions of desired outcomes necessary to evaluate and inspect an animal care and use program. Relevant references for the *Guide* and the PHS Policy are noted. Endnotes are included to reference specific U.S. Department of Agriculture (USDA) regulatory requirements that differ from the PHS Policy. Topics that are new to this version of the checklist or identified as a "must" in the *Guide* are highlighted. A column to identify changes that have occurred in the institution's program for animal care and use (PHS Policy [IV.A.1.a.-i.](#)) since the last review is also a new feature.

The checklist consists of the following sections:

- I. Semiannual Program Review Checklist
 - Institutional Policies and Responsibilities
 - Veterinary Care
- II. Semiannual Facility Inspection Checklist
 - Terrestrial Animal Housing and Support Areas
 - Aquatic Animal Housing and Support Areas
 - Cagewash
 - Special Facilities: Aseptic Surgery
 - Special Facilities: Procedure Areas, Non-survival Surgeries, Laboratories, Rodent Surgeries, Imaging, Whole Body Irradiation, Hazardous Agent Containment, Behavioral Studies
- III. Semiannual Program Review and Facility Inspection Report
- IV. Endnotes

It is recommended that the Program Review section be completed during an IACUC meeting. Because physical aspects of a program require visual observation to evaluate, it is recommended that the Facility Inspection section be completed during an inspection of the facilities, including satellite facilities.

A table is provided, "Semiannual Program Review and Facility Inspection Report," as a format for the IACUC to organize and track information regarding deficiencies, and plans and schedules for correction. IACUCs may choose to attach the table to the Semiannual Report to the Institutional Official.

Questions or comments?

Suggestions or comments about this checklist should be e-mailed to: olawdpe@mail.nih.gov.

h. Animals that fail to adapt are removed from study (<i>Guide, p 29</i>)	✓				
i. Appropriate observation intervals of restrained animals are provided (<i>Guide, p 29</i>)	✓				
j. Veterinary care is provided if lesions or illness result from restraint (<i>Guide, p 30</i>) [must]	✓				
k. Explanations of purpose and duration of restraint are provided to study personnel (<i>Guide, p 30</i>)	✓				
l. Major versus minor surgical procedures are evaluated on a case-by-case basis (<i>Guide, p 30</i>)	✓				
m. Multiple survival surgical procedure justifications in non-regulated species conform to regulated species standards (<i>Guide, p 30</i>)	✓				
n. Animals on food/fluid restriction are monitored to ensure nutritional needs are met (<i>Guide, p 31</i>)	✓				
o. Body weights for food/fluid restricted animals are recorded at least weekly (<i>Guide, p 31</i>)	✓				
p. Daily written records are maintained for food/fluid restricted animals (<i>Guide, p 31</i>)	✓				
q. Pharmaceutical grade chemicals are used, when available, for animal-related procedures (<i>Guide, p 31</i>)	✓				
r. Non-pharmaceutical grade chemicals are described, justified, and approved by IACUC (<i>Guide, p 31</i>)	✓				
s. Investigators conducting field studies know zoonotic diseases, safety issues, laws and regulations applicable in study area (<i>Guide, p 32</i>)	✓				
t. Disposition plans are considered for species removed from the wild (<i>Guide, p 32</i>)	✓				
u. Toe-clipping only used when no alternative, performed aseptically and with pain relief (<i>Guide, p 75</i>)	✓				

5. IACUC Membership and Functions A* M S C NA

a. IACUC is comprised of at least 5 members, appointed by CEO (PHS Policy, IV.A.3.)	✓				
b. Members include a veterinarian, a scientist, a nonscientist, and a nonaffiliated non-lab animal user (<i>Guide, p 24</i>) ⁱⁱ	✓				
c. IACUC authority and resources for oversight and evaluation of institution's program are provided (<i>Guide, p 14</i>)	✓				
d. IACUC conducts semiannual evaluations of institutional animal care and use program (PHS Policy, IV.B.)	✓				
e. Conducts semiannual inspections of institutional animal facilities (PHS Policy, IV.B.)	✓				
f. IACUC organizationally reports to the Institutional Official (PHS Policy, IV.A.1.b.)	✓				
g. Methods for reporting and investigating animal welfare concerns are in place (<i>Guide, p 23</i>) [must]	✓				
h. Reviews and investigates concerns about animal care and use at institution ⁱⁱⁱ (PHS Policy, IV.B.)	✓				
i. Procedures are in place for review, approval, and suspension of animal activities ^{iv} (PHS Policy, IV.B.)	✓				
j. Procedures are in place for review and approval of significant changes to approved activities (PHS Policy, IV.B.)	✓				
k. Policies are in place for special procedures (e.g., genetically modified animals, restraint, multiple survival surgery, food and fluid regulation, field investigations, agricultural animals) (<i>Guide, p 27-32</i>)	✓				
l. Requests for exemptions from major survival surgical procedure restrictions are made to USDA/APHIS ^v (<i>Guide, p 30</i>) [must]	✓				

6. IACUC Training A* M S C NA

a. All IACUC members should receive:					
b. Formal orientation to institution's program (<i>Guide, p 17</i>)	✓				
c. Training on legislation, regulations, guidelines, and policies (<i>Guide, p 17</i>)	✓				
d. Training on how to inspect facilities and labs where animal use or housing occurs (<i>Guide, p 17</i>)	✓				
e. Training on how to review protocols as well as evaluate the program (<i>Guide, p 17</i>)	✓				
f. Ongoing training/education (<i>Guide, p 17</i>)	✓				

7. IACUC Records and Reporting Requirements^{vi} A* M S C NA

h. Training is documented (<i>Guide</i> , p 15)	✓				
i. Training program content includes: (<i>Guide</i> , p 17)					
j. Methods for reporting concerns (<i>Guide</i> , p 17)	✓				
k. Humane practices of animal care (e.g., housing, husbandry, handling) ^{xii}	✓				
l. Humane practices of animal use (e.g., research procedures, use of anesthesia, pre- and post-operative care, aseptic surgical techniques and euthanasia (<i>Guide</i> , p 17) ^{xiii}	✓				
m. Research/testing methods that minimize numbers necessary to obtain valid results (PHS Policy, IV.A.1.g.)	✓				
n. Research/testing methods that minimize animal pain or distress (PHS Policy, IV.A.1.g.)	✓				
o. Use of hazardous agents, including access to OSHA chemical hazard notices where applicable (<i>Guide</i> , p 20)	✓				
p. Animal care and use legislation (<i>Guide</i> , p 17)	✓				
q. IACUC function (<i>Guide</i> , p 17)	✓				
r. Ethics of animal use and Three R's (<i>Guide</i> , p 17)	✓				

10. Occupational Health and Safety of Personnel

See attachment

* **A** = acceptable

M = minor deficiency

S = significant deficiency (is or may be a threat to animal health or safety)

C = change in program (PHS Policy [IV.A.1.a.-i.](#)) (include in semiannual report to IO and in annual report to OLAW)

NA = not applicable

2.31(d)(1)(x) - "No animal will be used in more than one major operative procedure from which it is allowed to recover, unless justified for scientific reasons by the principal investigator, in writing..."

^{xi} 2.33(a)(1) - "In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility." [USDA requirement additional]

^{xii} 2.32(c) - "Humane methods of animal maintenance and experimentation, including the basic needs of each species, proper handling and care for the various species of animals used by the facility, proper pre-procedural and post-procedural care of animals, and aseptic surgical methods and procedures."

^{xiii} 2.32(c) - additional specifications include:

- "proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility"
- "methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility..."
- "utilization of services (e.g., National Agricultural Library, National Library of Medicine) to provide information on appropriate animal care and use, alternatives to the use of live animals in research, that could prevent unintended and unnecessary duplication of research involving animals, and regarding the intent and requirements of the Act." [USDA training specifications are more detailed than PHS Policy].

10. Occupational Health and Safety of Personnel					
Employee Occupational Health Services (EOHS)		A	M	S	C NA
1.	Program is in place and is consistent with federal, state, and local regulations.	✓			
2.	Program covers all personnel who work or inspect laboratory animal facilities	✓			
3.	Rules and Guidelines-Safe work practices and procedures	✓			
4.	Medical Monitoring- Health Assessment program	✓			
5.	Personnel training is provided based on risk (e.g., zoonoses, hazards, personal hygiene, special precautions, animal allergies)	✓			
Program for medical evaluation and preventive medicine for personnel includes:					
6.	Pre-placement evaluation including health history	✓			
7.	Immunizations as appropriate (e.g., rabies, tetanus) and tests as appropriate	✓			
8.	Zoonosis surveillance as appropriate (e.g. Q-fever, tularemia, Hantavirus, plague)	✓			
9.	Procedures for reporting and treating injuries, including accidents bites, allergies, etc.	✓			
10.	Promotes early diagnosis of allergies including preexisting conditions	✓			
11.	Considers confidentiality and other legal factors as required by federal, state and local regulations [Must]	✓			
12.	If serum samples are collected, the purpose is consistent with federal and state laws [Must]				✓
Special precautions for personnel who work with nonhuman primates, their tissues or body fluids include:					
13.	Tuberculosis screening provided for all exposed personnel	✓			
14.	Training and implementation for procedures for bites, scratches, or injuries associated with macaques	✓			
15.	Recommends PPE to be worn including gloves, arm protection, face masks, face shields or goggles	✓			
16.	Injuries associated with macaques are carefully evaluated and treatment implemented	✓			
17.	Occupational safety and health of field studies is reviewed by EOHS committee or office	✓			
Chemical Safety - Safety and Risk Services (SRS)		A	M	S	C NA
1.	Risk Assessment - defining and quantifying chemical hazards	✓			
2.	Chemical Safety Program - avoiding and controlling hazards and exposures	✓			
3.	Recordkeeping- monitor safety programs and identify deficiencies	✓			
4.	Personnel conduct visits to laboratories and facilities, where hazardous agents may be present, to determine compliance with institutional, city, state, and federal regulations.	✓			
5.	Provides training in chemical safety, work safety, respirator use and fitness, etc. for university personnel with potential contact with hazardous substances.	✓			
6.	Provide additional monitoring, training, and consultation if needed.	✓			
7.	Chemical hazard risks are determined by reviewing the MSDS, experimental protocol, and specific agent	✓			
8.	Makes recommendations such as PPE to include respirators, gloves, etc.	✓			
9.	Inspects laboratories and the ARF as needed to include fire safety, electrical/mechanical safety, storage and housekeeping, compressed gases, and chemical and laboratory safety.	✓			
Radiation Safety – Radiation Safety Office (RS)		A	M	S	C NA
1.	Risk Assessment - defining and quantifying radiological hazards	✓			
2.	Radiation Safety Program- avoiding and controlling hazards and exposures	✓			
3.	Personnel conduct visits to laboratories and facilities, where radioactive materials may be present, to determine compliance with institutional, city, state, and federal regulations.	✓			
4.	Provides training in radiation safety for university personnel with potential contact with radioactive materials.	✓			
5.	Provide additional monitoring, training, and consultation as needed.	✓			
6.	Clears radioisotope exposed cages and waste for disposal or transfer to the cage wash area.	✓			
7.	Establishes policies and rules for radiation control and safety, and reviews research protocols for the use of sources of ionizing radiation.	✓			
8.	Oversees the collection, use, transportation, and disposal of radioactive materials.	✓			

End Notes

ⁱ The PHS Policy requires that Assured institutions comply with the regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act, as applicable. The endnotes below are specific USDA regulatory requirements that differ from or are in addition to the PHS Policy. This list is not intended to be all inclusive. For additional information please refer to 9 CFR Subchapter A - Animal Welfare.

ⁱⁱ Part 2 Subpart C - Research Facilities

- 2.31(b)(2) - "The Committee shall be composed of a Chairman and at least two additional members;... at least one shall not be affiliated in any way with the facility...such person will provide representation for general community interests in the proper care and treatment of animals." [PHS policy requires 5 members]

ⁱⁱⁱ 2.32(c)(4) - "...No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act." [USDA requirement additional to PHS Policy]

^{iv} 2.31(d)(5) - "...shall conduct continuing reviews of activities...not less than annually." [PHS Policy requires a complete new review every 3 years utilizing all the criteria for initial review]

^v 2.31(d)(1)(x) - "...no animal will be used in more than one major operative procedure from which it is allowed to recover unless...(it is) justified for scientific reasons...(or is) required as routine veterinary procedure...or other special circumstances as determined by the Administrator on an individual basis." [this last point is an additional USDA justification for multiple survival surgeries]

^{vi} 2.36 - "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]

^{vii} 2.36(b)(3) - "...exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such exceptions must be attached to the facility's annual report." [Refers to USDA annual report]

^{viii} 2.31(c)(3) - "...Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the institutional official, to APHIS and any Federal agency funding that activity." [PHS Policy requires prompt reporting to OPRR of serious or continuing noncompliance with the PHS Policy or serious deviations from the provisions of the *Guide*]

^{ix} 2.36 - "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]

^{*} In addition to PHS requirements for IACUC review/application for funding, USDA regulations require:

2.31(d)(1)(ii) - "The principal investigator (PI) consider alternatives to procedures that cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources...used to determine that alternatives were not available."

2.31(d)(1)(iii) - "The PI has provided written assurance that the activities do not unnecessarily duplicate previous experiments."

2.31(d)(1)(iv) - "Procedures that may cause more than momentary or slight pain or distress to the animals will:
- involve in their planning, consultation with the attending veterinarian or his or her designee; [PHS Policy does not specify veterinary consultation]
- not include paralytics without the use of anesthesia;"

2.31(d)(1)(x) - "No animal will be used in more than one major operative procedure from which it is allowed to recover, unless justified for scientific reasons by the principal investigator, in writing..."

^{xi} 2.33(a)(1) - "In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility." [USDA requirement additional]

^{xii} 2.32(c) - "Humane methods of animal maintenance and experimentation, including the basic needs of each species, proper handling and care for the various species of animals used by the facility, proper pre-procedural and post-procedural care of animals, and aseptic surgical methods and procedures."

^{xiii} 2.32(c) - additional specifications include:

- "proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility"
- "methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility..."
- "utilization of services (e.g., National Agricultural Library, National Library of Medicine) to provide information on appropriate animal care and use, alternatives to the use of live animals in research, that could prevent unintended and unnecessary duplication of research involving animals, and regarding the intent and requirements of the Act." [USDA training specifications are more detailed than PHS Policy].

10. Occupational Health and Safety of Personnel					
Employee Occupational Health Services (EOHS)		A	M	S	C NA
1.	Program is in place and is consistent with federal, state, and local regulations.	✓			
2.	Program covers all personnel who work or inspect laboratory animal facilities	✓			
3.	Rules and Guidelines-Safe work practices and procedures	✓			
4.	Medical Monitoring- Health Assessment program	✓			
5.	Personnel training is provided based on risk (e.g., zoonoses, hazards, personal hygiene, special precautions, animal allergies)	✓			
Program for medical evaluation and preventive medicine for personnel includes:					
6.	Pre-employment evaluation including health history	✓			
7.	Immunizations as appropriate (e.g., rabies, tetanus) and tests as appropriate	✓			
8.	Zoonosis surveillance as appropriate (e.g. Q-fever, tularemia, Hantavirus, plague)	✓			
9.	Procedures for reporting and treating injuries, including accidents bites, allergies, etc.	✓			
10.	Promotes early diagnosis of allergies including preexisting conditions	✓			
11.	Considers confidentiality and other legal factors as required by federal, state and local regulations [Must]	✓			
12.	If serum samples are collected, the purpose is consistent with federal and state laws [Must]				✓
Special precautions for personnel who work with nonhuman primates, their tissues or body fluids include:					
13.	Tuberculosis screening provided for all exposed personnel	✓			
14.	Training and implementation for procedures for bites, scratches, or injuries associated with macaques	✓			
15.	Recommends PPE to be worn including gloves, arm protection, face masks, face shields or goggles	✓			
16.	Injuries associated with macaques are carefully evaluated and treatment implemented	✓			
17.	Occupational safety and health of field studies is reviewed by EOHS committee or office	✓			
Chemical Safety - Safety and Risk Services (SRS)		A	M	S	C NA
1.	Risk Assessment - defining and quantifying chemical hazards	✓			
2.	Chemical Safety Program - avoiding and controlling hazards and exposures	✓			
3.	Recordkeeping- monitor safety programs and identify deficiencies	✓			
4.	Personnel conduct visits to laboratories and facilities, where hazardous agents may be present, to determine compliance with institutional, city, state, and federal regulations.	✓			
5.	Provides training in chemical safety, work safety, respirator use and fitness, etc. for university personnel with potential contact with hazardous substances.	✓			
6.	Provide additional monitoring, training, and consultation if needed.	✓			
7.	Chemical hazard risks are determined by reviewing the MSDS, experimental protocol, and specific agent	✓			
8.	Makes recommendations such as PPE to include respirators, gloves, etc.	✓			
9.	Inspects laboratories and the ARF as needed to include fire safety, electrical/mechanical safety, storage and housekeeping, compressed gases, and chemical and laboratory safety.	✓			
Radiation Safety – Radiation Safety Office (RS)		A	M	S	C NA
1.	Risk Assessment - defining and quantifying radiological hazards	✓			
2.	Radiation Safety Program- avoiding and controlling hazards and exposures	✓			
3.	Personnel conduct visits to laboratories and facilities, where radioactive materials may be present, to determine compliance with institutional, city, state, and federal regulations.	✓			
4.	Provides training in radiation safety for university personnel with potential contact with radioactive materials.	✓			
5.	Provide additional monitoring, training, and consultation as needed.	✓			
6.	Clears radioisotope exposed cages and waste for disposal or transfer to the cage wash area.	✓			
7.	Establishes policies and rules for radiation control and safety, and reviews research protocols for the use of sources of ionizing radiation.	✓			
8.	Oversees the collection, use, transportation, and disposal of radioactive materials.	✓			

Biological Safety - Biohazard Compliance Office (BHC)		A	M	S	C	NA
1.	Inspects biological laboratories associated with IBC protocols and provides appropriate biosafety level signage.	✓				
2.	Risk Assessment -defining and quantifying biological risks	✓				
3.	Training and Education- biosafety practices, spill clean-up procedures, proper use of BSCs, biological agent shipping, hazardous communication and emergency response procedures	✓				
4.	Recordkeeping- monitors safety programs and identifies deficiencies	✓				
5.	Provides additional monitoring, training, and consultation as needed	✓				
6.	Biological risks are assessed by BHC and the IBC using the CDC publication BMBL (Biosafety in Microbiological and Biomedical Laboratories), NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, American Biological Safety Association & American Society for Microbiology publications, peer review journals and professional and governmental sources.	✓				
7.	Provides recommendations on PPE use including PAPRs, N-95 respirators, lab coats, coveralls, gloves, face and eye protection, and shoe-covers.	✓				
8.	Provides regulatory guidance on biological research	✓				

Reviewed by the IACUC on September 19, 2019.