




Research Support Services  
Institutional Animal Care and Use Committee  
San Diego State University  
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DATE: May 28, 2020

TO: Stephen C. Welter  
Vice President for Research

VIA: Rick Gulizia  
Asst. Vice President  
Research Support Services

FROM: Todd Anderson, Chair   
Institutional Animal Care and Use Committee

SUBJECT: Spring 2020 Semi-annual Facility Inspection and Program Review Reports

Our Institution adheres to the recommendations of the Guide, the PHS Policy, and the Animal Welfare Act and Regulations, all of which are used as a foundation for the development, implementation, and continual improvement of a comprehensive animal care and use program based on humane care and use of animals.

As a result of the coronavirus outbreak, the facility inspections were conducted using Measures outlined in NIH/OLAW NOT-OD-20-088 were implemented to perform these inspections by qualified individuals/ad-hoc consultants including a facility manager and Principal Investigators. The OLAW Semi-annual Facility Inspection Checklist (based on the 8<sup>th</sup> Edition *ILAR Guide for the Care and Use of Laboratory Animals*) was used as a guideline. The following definitions were used to determine the categories of compliance: A= acceptable; met or exceeded USDA and NIH standards; M= minor deficiency; items not affecting animal health or safety; S= significant deficiency (items that are or may be a direct threat to human or animal health and safety where animals are involved in the research); C=Change which will be submitted to OLAW; N/A=Not applicable. There is a list of minor deficiencies found during these inspections and which are outlined in the attached documents. These reports were discussed and approved by the IACUC at their meeting on May 11, 2020.

Additionally, the IACUC reviewed and approved the program review at the convened meeting on April 13, 2020. The OLAW Semiannual Program Review Checklist based on the 8<sup>th</sup> Edition of the *ILAR Guide for the Care and Use of Laboratory Animals* was used as a guideline. As



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reported before there remains an ongoing concern. The components of the occupational health and safety program for medical evaluation and preventative medicine for those working with vertebrate animals are in place however, the IACUC requested better monitoring and adherence to the program due to an increased number of gaps in documentation. Additionally, the IACUC recommended moving from a paper-based system to an electronic monitoring system to accommodate more efficient and effective compliance as well as future growth in the use of animals. A letter has been sent to EH&S Senior Director outlining the IACUC's concerns.

There have not been any departures from the regulations submitted, reviewed and/or approved over the last 6 months.



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**IACUC approved May 11, 2020**

These inspections took place, as per the regular schedule, after the University closed due to the COVID-19 pandemic. Measures outlined in NIH/OLAW NOT-OD-20-088 were implemented to perform these inspections by qualified individuals/ad-hoc consultants including a facility manager and Principal Investigators.

The SDSU Office of Laboratory Animal Care and Principal Investigators continue to care for the animals being housed and used in research by perform normal husbandry, health checks and notifications to the PI, as necessary. No USDA covered species are being housed.

- The inspections for OHS requirements were conducted by the Veterinarian using the OLAW recommended facility inspection checklist.
- Controlled substance inspection is in progress. The duty has been assigned to another person in EH&S.
- Throughout all applicable facilities and rooms, CO2 rates will be recalculated and posted to meet the requirements of the 2020 AMVA Guidelines for Euthanasia. The posted flow rates will include brief instructions for lab owned CO2 euthanasia chambers.

**#1 Vivarium – Conducted April 7, 2020 – Veterinarian and member #16**

Deficiency Category	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date correction completed
A	Clean side of autoclave	One of two autoclaves do not work.	OLAC	One working autoclave sufficient for workload	
A	Housing		PI		



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A	Housing & Procedure Room		PI		
A	Housing		PIs		
A	Housing		PI		
A	Procedure Room		PIs		
A	Animal Food Storage		OLAC		
A	Hallway/Surgery Anteroom		OLAC / PIs		
M *repeat	Surgery Room	Discard expired povidone iodine solution.	PIs		
A	Surgery Recovery		PIs		
A	Housing		EH&S/OLAC		
A	ABSL2 Gowning/Anteroom		OLAC / PI		
A	Housing	No animal housing at this time.			
A	Quarantine		Multiple PIs		
A	Housing		PI		
A	Procedure Room		PI		
A	ABSL2 Anti Room Gowning		OLAC		
A	ABSL-2 Room		EH&S/OLAC		
A	LS-21 – Autoclave		OLAC		



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**#2 Vivarium – Conducted April 7, 2020 Veterinarian and Member #16**

Deficiency Category	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date correction completed
A	Housing		PI		
A	Procedure Room	Room currently not being used.			
A	Housing	No animals housed at this time.			
A	Housing	No animals housed at this time.			
A	Procedure Room		PI		
A	Housing		PIs		
A	Cage Wash Clean Side		OLAC/EH&S		
A	Cage Wash Dirty Side		OLAC		

**#3 Vivarium – Conducted April 7, 2020 – Veterinarian and Member #16**

Deficiency Category	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date correction completed
A	Testing Room		PI		
A	Testing Room		PI		



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A	Testing Room		PI		
A	Entry area		OLAC		
A	Housing		PI		
A	Testing Room		PI		
A	Testing Room		PIs		
A	Housing		PI		
A	Survival Surgery / Procedure room		PI		
A	Housing		PI		
A	Testing Room		PI		
A	Wet Lab		PIs		
A	Procedure/Testing Room		PI		
A	Hallway outside this room		OLAC/Facilities		
A	Surgery / Procedure Room		PI		
A	Bedding Closet		OLAC		
A	Testing Room		EH&S/OLAC/College of Sciences		
A	Testing Room		PI		
A	Testing Room		PI		
A	Testing Room		PI		
A	Testing Room	Not inspected, testing in progress	PI		
A	Testing Room		PI		



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A	Housing		PI		
A	Housing		PI		
A	Housing		PI		
A	Hallway outside this room		College of Sciences		
A	Cagewash		OLAC/EH&S		
M	Testing Room		PI/Facilities/OLAC		
A	Feed and Bedding Storage		OLAC		

**Laboratories – Conducted April 7, 2020 – Veterinarian and Member #16**

Deficiency Category	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date correction completed
A	Lab 1	Acceptable	PI		
A	Lab 2	Acceptable	PI		

**Satellite Laboratory/Facility April 3, 2020 – This inspection was conducted by the facility manager. The OLAW suggested checklist was used.**

Deficiency Category	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date correction completed
	Facility not inspected.	No research animals being housed at the present time.			

**#4 Housing April 6, 2020 - This inspection was conducted by the PI using the OLAW suggested checklist.**

Deficiency Category	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date correction completed
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The PI noted that there have been no modifications to the zebrafish care during this COVID-19 crisis. They are receiving the same daily care from either the PI (Thursday-Monday) or lab member (Tuesday-Wednesday).

A	Housing	Acceptable – No deficiencies noted.	PI		
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#### #5 Housing – April 10, 2020 – This inspection was conducted by the PI.

A	Satellite Facility		PI		
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Housing started at this satellite facility on March 29, 2020.

The chicken coop at the facility has ample space for the two sets of five chickens (10 total). The entire chicken coop was physically split in half with wire mesh. On the interior of the chicken coop each set of five chickens are housed in approximately 60 ft.<sup>2</sup> of space. In addition to the interior space the chickens also have an outside protected run. Each half of the outside run also has approximately 60 ft.<sup>2</sup> of space. Each half of the internal space has a 5 gallon container for water (2 total), an approximately 4 gallon container of food (2 total), a heat lamp (2 total), and perches/roosts for all 10 chickens.

The chickens are checked on at minimum once per day, but more often than not, two to three times per day. All 10 chickens are quite healthy and are continuing to grow very robustly. Even though the water containers hold 5 gallons of water (and thus would only need to be filled approximately once per week), the PI has been continuing to use and add fresh water to the small water containers. The content of the food containers is monitored on a daily basis, as well as the large water containers. The large water containers are normally dumped and cleaned with soap and water approximately every third day. The diets of the chickens have been enhanced with dry mealworms, as well as a product purchased off Amazon.com and referred to as "Chick Sticks".

Records of the daily care for the chickens in a chicken husbandry log book. Because of the age of the chickens, as well as the less than optimal weather conditions they've been experiencing in March and April, the PI only allows the chickens into the outside run once per day for approximately 30 minutes. As the chickens become older, and the weather becomes more optimal, the doors to the outside chicken run we'll be opened in the mornings, and then closed again in the evening (unless the weather becomes very warm and then the chickens will have access to the outside run 24 hours per day).





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The information provided by the PI was reviewed and found to be acceptable.

### Controlled Substances

Deficiency Category	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date correction completed
Inspection is in progress. One lab remains pending. Labs working with animals who also use controlled substances have been found compliant with regulations.					

### Occupational Health and Safety of personnel working with animals

Deficiency Category	Location	Deficiency and Plan for Correction	Responsible Party	Correction Schedule and Interim Status	Date correction completed
This inspection was conducted by the Veterinarian using the OLAW facility inspection checklist.					

## San Diego State University – Spring 2020 – Approved IACUC at meeting on April 13, 2020 Institutional Animal Care and Use Committee - Semiannual Program Review

On April 13, 2020 the IACUC performed and approved the Semi-annual Program Review using the OLAW Semi-annual Program Review Checklist (based on the 8<sup>th</sup> Edition of the Guide for the Care and Use of Laboratory Animals) as a guideline.

### I. Semiannual Program Review Checklist<sup>i</sup> Institutional Policies and Responsibilities

- \* **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

1. Animal Care and Use Program <b>NEW</b>	A*	M	S	C	NA
• Responsibility for animal well-being is assumed by all members of the program ( <i>Guide</i> , <a href="#">p 1</a> ) <b>[must]</b>	X				
• IO has authority to allocate needed resources ( <i>Guide</i> , <a href="#">p 13</a> )	X				
• Resources necessary to manage program of veterinary care are provided ( <i>Guide</i> , <a href="#">p 14</a> ) <b>[must]</b>	X				
• Sufficient resources are available to manage the program, including training of personnel in accord with regulations and the <i>Guide</i> ( <i>Guide</i> , <a href="#">pp 11, 15</a> )	X				
• Program needs are regularly communicated to IO by AV and/or IACUC ( <i>Guide</i> , <a href="#">p 13</a> )	X				
• Responsibilities for daily animal care and facility management are assigned to specific individual(s) when a full-time veterinarian is not available on site ( <i>Guide</i> , <a href="#">p 14</a> ) <b>[must]</b>	X				
• Inter-institutional collaborations are described in formal written agreements ( <i>Guide</i> , <a href="#">p 15</a> )	X				
• Written agreements address responsibilities, animal ownership, and IACUC oversight ( <i>Guide</i> , <a href="#">p 15</a> )	X				
2. Disaster Planning and Emergency Preparedness <b>NEW</b>	A*	M	S	C	NA

<ul style="list-style-type: none"> <li>Disaster plans for each facility to include satellite locations are in place (<i>Guide, p 35, p 75</i>) [must]</li> </ul>	X				
<ul style="list-style-type: none"> <li>Plans include provisions for euthanasia (<i>Guide, p 35</i>) [must]</li> </ul>	X				
<ul style="list-style-type: none"> <li>Plans include triage plans to meet institutional and investigators' needs (<i>Guide, p 35</i>)</li> </ul>	X				
<ul style="list-style-type: none"> <li>Plans define actions to prevent animal injury or death due to HVAC or other failures (<i>Guide, p 35</i>)</li> </ul>	X				
<ul style="list-style-type: none"> <li>Plans describe preservation of critical or irreplaceable animals (<i>Guide, p 35</i>)</li> </ul>	X				
<ul style="list-style-type: none"> <li>Plans include essential personnel and their training (<i>Guide, p 35</i>)</li> </ul>	X				
<ul style="list-style-type: none"> <li>Animal facility plans are approved by the institution and incorporated into overall response plan (<i>Guide, p 35</i>)</li> </ul>	X				
<ul style="list-style-type: none"> <li>Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place (<i>Guide, p 35</i>)</li> </ul>	X				
<b>3. IACUC</b> <b>NEW</b>	<b>A*</b>	<b>M</b>	<b>S</b>	<b>C</b>	<b>NA</b>
<ul style="list-style-type: none"> <li>Meets as necessary to fulfill responsibilities (<i>Guide, p 25</i>) [must]</li> </ul>	X				
<ul style="list-style-type: none"> <li>IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions (<i>Guide, p 26</i>) [must]</li> </ul>	X				
<ul style="list-style-type: none"> <li>Continuing IACUC oversight after initial protocol approval is in place (<i>Guide, p 33</i>)</li> </ul>	X				
<ul style="list-style-type: none"> <li>IACUC evaluates the effectiveness of training programs (<i>Guide, p 15</i>)</li> </ul>	X				
<b>4. IACUC Protocol Review - Special Considerations</b>	<b>A*</b>	<b>M</b>	<b>S</b>	<b>C</b>	<b>NA</b>
<ul style="list-style-type: none"> <li>Humane endpoints are established for studies that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, and models of cardiovascular shock (<i>Guide, p 27</i>)</li> </ul>	X				
<ul style="list-style-type: none"> <li>For pilot studies, a system to communicate with the IACUC is in place (<i>Guide, p 28</i>)</li> </ul>	X				
<ul style="list-style-type: none"> <li>For genetically modified animals, enhanced monitoring and reporting is in place (<i>Guide, p 28</i>)</li> </ul>	X				
<ul style="list-style-type: none"> <li>Restraint devices are justified in the animal use protocols (<i>Guide, p 29</i>) [must]</li> </ul>	X				
<ul style="list-style-type: none"> <li>Alternatives to physical restraint are considered (<i>Guide, p 29</i>)</li> </ul>	X				
<ul style="list-style-type: none"> <li>Period of restraint is the minimum to meet scientific objectives (<i>Guide, p 29</i>)</li> </ul>	X				
<ul style="list-style-type: none"> <li>Training of animals to adapt to restraint is provided (<i>Guide, p 29</i>)</li> </ul>	X				

• Animals that fail to adapt are removed from study ( <i>Guide</i> , <a href="#">p 29</a> )	X				
• Appropriate observation intervals of restrained animals are provided ( <i>Guide</i> , <a href="#">p 29</a> )*	X				
• Veterinary care is provided if lesions or illness result from restraint ( <i>Guide</i> , <a href="#">p 30</a> ) [must]	X				
• Explanations of purpose and duration of restraint are provided to study personnel ( <i>Guide</i> , <a href="#">p 30</a> )	X				
• Multiple surgical procedures on a single animal are justified and outcomes evaluated ( <i>Guide</i> , <a href="#">p 30</a> )	X				
• Major versus minor surgical procedures are evaluated on a case-by-case basis ( <i>Guide</i> , <a href="#">p 30</a> )	X				
• Multiple survival procedure justifications in non-regulated species conform to regulated species standards ( <i>Guide</i> , <a href="#">p 30</a> )	X				
• Animals on food/fluid restriction are monitored to ensure nutritional needs are met ( <i>Guide</i> , <a href="#">p 31</a> )	X				
• Body weights for food/fluid restricted animals are recorded at least weekly ( <i>Guide</i> , <a href="#">p 31</a> )	X				
• Daily written records are maintained for food/fluid restricted animals ( <i>Guide</i> , <a href="#">p 31</a> )	X				
• Pharmaceutical grade chemicals are used , when available, for animal-related procedures ( <i>Guide</i> , <a href="#">p 31</a> )	X				
• Non-pharmaceutical grade chemicals are described, justified, and approved by IACUC ( <i>Guide</i> , <a href="#">p 31</a> )	X				
• Investigators conducting field studies know zoonotic diseases, safety issues, laws and regulations applicable in study area ( <i>Guide</i> , <a href="#">p 32</a> )	X				
• Disposition plans are considered for species removed from the wild ( <i>Guide</i> , <a href="#">p 32</a> )	X				
• Toe-clipping only used when no alternative, performed aseptically and with pain relief ( <i>Guide</i> , <a href="#">p 75</a> )	X				
<b>5. IACUC Membership and Functions</b>	<b>A*</b>	<b>M</b>	<b>S</b>	<b>C</b>	<b>NA</b>
• IACUC is comprised of at least 5 members, appointed by CEO (PHS Policy, <a href="#">IV.A.3.</a> )	X				
• Members include a veterinarian, a scientist, a nonscientist, and a nonaffiliated non-lab animal user ( <i>Guide</i> , <a href="#">p 24</a> ) <sup>ii</sup>	X				
• IACUC authority and resources for oversight and evaluation of institution's program are provided ( <i>Guide</i> , <a href="#">p 14</a> )	X				

• IACUC conducts semiannual evaluations of institutional animal care and use program (PHS Policy, <a href="#">IV.B.</a> )	X				
• Conducts semiannual inspections of institutional animal facilities (PHS Policy, <a href="#">IV.B.</a> )	X				
• IACUC organizationally reports to the Institutional Official (PHS Policy, <a href="#">IV.A.1.b.</a> )	X				
• Methods for reporting and investigating animal welfare concerns are in place ( <i>Guide</i> , <a href="#">p 23</a> ) [must]	X				
• Reviews and investigates concerns about animal care and use at institution <sup>iii</sup> (PHS Policy, <a href="#">IV.B.</a> )	X				
• Procedures are in place for review, approval, and suspension of animal activities <sup>iv</sup> (PHS Policy, <a href="#">IV.B.</a> )	X				
• Procedures are in place for review and approval of significant changes to approved activities (PHS Policy, <a href="#">IV.B.</a> )	X				
• Review procedures/processes are in place for special research procedures ( <i>Guide</i> , <a href="#">p 27-32</a> )	X				
• Requests for exemptions from major survival surgical procedure restrictions are made to USDA/APHIS <sup>v</sup> ( <i>Guide</i> , <a href="#">p 30</a> ) [must]					X

## 6. IACUC Training NEW

**A\* M S C NA**

• All IACUC members should receive:					
❖ Formal orientation to institution's program ( <i>Guide</i> , <a href="#">p 17</a> )	X				
❖ Training on legislation, regulations, guidelines, and policies ( <i>Guide</i> , <a href="#">p 17</a> )	X				
❖ Training on how to inspect facilities and labs where animal use or housing occurs ( <i>Guide</i> , <a href="#">p 17</a> )	X				
❖ Training on how to review protocols as well as evaluate the program ( <i>Guide</i> , <a href="#">p 17</a> )	X				
❖ Ongoing training/education ( <i>Guide</i> , <a href="#">p 17</a> )	X				

## 7. IACUC Records and Reporting Requirements<sup>vi</sup>

**A\* M S C NA**

• Semiannual report to the IO (PHS Policy, <a href="#">IV.B.</a> )					
❖ Submitted to IO every 6 months	X				
❖ Compiles program review and facility inspection(s) results (includes all program and facility deficiencies)	X				
❖ Includes minority IACUC views	X				
❖ Describes IACUC-approved departures from the <i>Guide</i> or PHS Policy and the reasons for each departure <sup>vii</sup>	X				

❖ Distinguishes significant from minor deficiencies	X				
❖ Includes a plan and schedule for correction for each deficiency identified <sup>viii</sup>	X				
• Reports to OLAW (PHS Policy, <a href="#">IV.F.</a> )X					
❖ Annual report to OLAW documents program changes, dates of the semiannual program reviews and facility inspections and includes any minority views	X				
❖ Promptly advises OLAW of serious/ongoing <i>Guide</i> deviations or PHS Policy noncompliance ( <a href="#">NOT-OD-05-034</a> )X	X				
❖ Institute must promptly advise OLAW of any suspension of an animal activity by the IACUC ( <a href="#">NOT-OD-05-034</a> )X	X				
• Reports to U.S. Department of Agriculture (USDA) or Federal funding agency <sup>ix</sup>					
❖ Annual report to USDA contains required information including all exceptions/exemptions	X				
❖ Reporting mechanism to USDA is in place for IACUC-approved exceptions to the regulations and standards	X				
❖ Reports are filed within 15 days for failures to adhere to timetable for correction of significant deficiencies	X				
❖ Promptly reports suspensions of activities by the IACUC to USDA and any Federal funding agency	X				
• Records (PHS Policy, <a href="#">IV.E.</a> )					
❖ IACUC meeting minutes and semiannual reports to the IO are maintained for 3 years	X				
❖ Records of IACUC reviews of animal activities include all required information*	X				
❖ Records of IACUC reviews are maintained for 3 years after the completion of the study	X				

## 8. Veterinary Care (See also next section - Veterinary Care)

	A*	M	S	C	NA
• An arrangement for veterinarian(s) with training or experience in lab animal medicine is in place including backup veterinary care <sup>xi</sup>	X				
• Veterinary access to all animals is provided ( <i>Guide</i> , <a href="#">p 14</a> ) <b>[must]</b>	X				
• Direct or delegated authority is given to the veterinarian to oversee all aspects of animal care and use ( <i>Guide</i> , <a href="#">p 14</a> ) <b>[must]</b>	X				
• Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol ( <i>Guide</i> , <a href="#">p 5</a> ) <b>[must]</b>	X				
• Veterinarian provides consultation when interventional control is not possible	X				

(Guide, p 5) [must]					
• If part time /consulting veterinarian, visits meet programmatic needs (Guide, p 14)	X				
• Regular communication occurs between veterinarian and IACUC (Guide, p 14)	X				
• Veterinarian(s) have experience and training in species used (Guide, p 15) [must]	X				
• Veterinarian(s) have experience in facility administration/management (Guide, p 15)	X				
<b>9. Personnel Qualifications and Training</b>					
	<b>A*</b>	<b>M</b>	<b>S</b>	<b>C</b>	<b>NA</b>
• All personnel are adequately educated, trained, and/or qualified in basic principles of laboratory animal science. Personnel included: [must]					
o Veterinary/other professional staff (Guide, p 15-16)	X				
o IACUC members (Guide, p 17)	X				
o Animal care personnel (Guide, p 16)	X				
o Research investigators, instructors, technicians, trainees, and students (Guide, pp 16-17)	X				
• Continuing education for program and research staff provided to ensure high quality care and reinforce training (Guide, pp 16-17)	X				
• Training is available prior to starting animal activity (Guide, p 17)	X				
• Training is documented (Guide, p 15)	X				
• Training program content includes: (Guide, p 17)					
o Methods for reporting concerns (Guide, p 17)	X				
o Humane practices of animal care (e.g., housing, husbandry, handling) <sup>xii</sup>	X				
o Humane practices of animal use (e.g., research procedures, use of anesthesia, pre- and post-operative care, aseptic surgical techniques and euthanasia (Guide, p 17) <sup>xiii</sup>	X				
o Research/testing methods that minimize numbers necessary to obtain valid results (PHS Policy, IV.A.1.g.)	X				
o Research/testing methods that minimize animal pain or distress (PHS Policy, IV.A.1.g.)	X				
o Use of hazardous agents, including access to OSHA chemical hazard notices where applicable (Guide, p 20)	X				
o Animal care and use legislation (Guide, p 17)	X				
o IACUC function (Guide, p 17)	X				

○ Ethics of animal use and Three R's ( <i>Guide, p 17</i> )	X				
<b>10. Occupational Health and Safety of Personnel</b>	<b>A*</b>	<b>M</b>	<b>S</b>	<b>C</b>	<b>NA</b>
• Program is in place and is consistent with federal, state, and local regulations ( <i>Guide, p 17</i> ) [must]	X				
• Program covers <i>all</i> personnel who work in laboratory animal facilities ( <i>Guide, p 18</i> )	X				
• Changing, washing, and showering facilities are available as appropriate ( <i>Guide, p 19</i> )	X				
• Hazardous facilities are separated from other areas and identified as limited access ( <i>Guide, p 19</i> )	X				
• Personnel training is provided based on risk (e.g., zoonoses, hazards, personal hygiene, special precautions, animal allergies) ( <i>Guide, p 20</i> )	X				
• Personal hygiene procedures are in place (e.g., work clothing, eating/drinking/smoking policies) ( <i>Guide, p 20</i> )	X				
• Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place ( <i>Guide, p 21</i> )	X				
• Personal Protective Equipment for the work area is appropriate and available ( <i>Guide, p 21</i> )	A				
• Program for medical evaluation and preventive medicine for personnel includes:					
○ Pre-employment evaluation including health history ( <i>Guide, p 22</i> )	X				
○ Immunizations as appropriate (e.g., rabies, tetanus) and tests as appropriate ( <i>Guide, p 22</i> )	X				
○ Zoonosis surveillance as appropriate (e.g., Q-fever, tularemia, Hantavirus, plague) ( <i>Guide, p 23</i> )	X				
○ Procedures for reporting and treating injuries, including accidents, bites, allergies, etc. ( <i>Guide, p 23</i> )	X				
○ Promotes early diagnosis of allergies including preexisting conditions ( <i>Guide, p 22</i> )	X				
○ Considers confidentiality and other legal factors as required by federal, state and local regulations ( <i>Guide, p 22</i> ) [must]	X				
○ If serum samples are collected, the purpose is consistent with federal and state laws ( <i>Guide, p 22</i> ) [must]	X				
• Waste anesthetic gases are scavenged ( <i>Guide, p 21</i> )	X				
• Hearing protection is provided in high noise areas ( <i>Guide, p 22</i> )	X				



• Respiratory protection is available when performing airborne particulate work ( <i>Guide, p 22</i> )	X				
• Special precautions for personnel who work with nonhuman primates, their tissues or body fluids include:					
○ Tuberculosis screening provided for all exposed personnel ( <i>Guide, p 23</i> )	X				
○ Training and implementation of procedures for bites, scratches, or injuries associated with macaques ( <i>Guide, p 23</i> )	X				
○ PPE is provided including gloves, arm protection, face masks, face shields, or goggles ( <i>Guide, p 21</i> )	X				
○ Injuries associated with macaques are carefully evaluated and treatment implemented ( <i>Guide, p 23</i> )	X				
• Occupational safety and health of field studies is reviewed by OSH committee or office ( <i>Guide, p 32</i> )	X				
<b>11. Personnel Security</b> <span style="background-color: yellow;">NEW</span>	<b>A*</b>	<b>M</b>	<b>S</b>	<b>C</b>	<b>NA</b>
• Preventive measures in place include pre-employment screening, and physical and IT security ( <i>Guide, p 23</i> )	X				
<b>12. Investigating &amp; Reporting Animal Welfare Concerns</b> <span style="background-color: yellow;">NEW</span>	<b>A*</b>	<b>M</b>	<b>S</b>	<b>C</b>	<b>NA</b>
• Methods for investigating and reporting animal welfare concerns are established ( <i>Guide, p 23</i> ) <span style="background-color: cyan;">[must]</span>	X				
• Reported concerns and corrective actions are documented ( <i>Guide, p 24</i> )	X				
• Mechanisms for reporting concerns are posted in facility and at applicable website with instructions ( <i>Guide, p 24</i> )	X				
○ Includes multiple contacts ( <i>Guide, p 24</i> )	X				
○ Includes anonymity, whistle blower policy, nondiscrimination and reprisal protection ( <i>Guide, p 24</i> )	X				

## Veterinary Care

1. Clinical Care and Management <small>NEW</small>						A*	M	S	C	NA
• Veterinary program offers high quality of care and ethical standards ( <i>Guide, p 105</i> ) <b>[must]</b>						X				
• Veterinarian provides guidance to all personnel to ensure appropriate husbandry, handling, treatment, anesthesia, analgesia, and euthanasia ( <i>Guide, p 106</i> )						X				
• Veterinarian provides oversight to surgery and perioperative care ( <i>Guide, p 106</i> )						X				
• Veterinary care program is appropriate for program requirements ( <i>Guide, pp 113-114</i> )						X				
• Veterinarian(s) is familiar with species and use of animals and has access to medical and experimental treatment records ( <i>Guide, p 114</i> )						X				
• Procedures to triage and prioritize incident reports are in place ( <i>Guide, p 114</i> )						X				
• Procedures are in place to address:										
o Problems with experiments to determine course of treatment in consultation with investigator( <i>Guide, p 114</i> )						X				
o Recurrent or significant health problems with the IACUC and documentation of treatments and outcomes ( <i>Guide, p 114</i> )						X				
o Veterinary review and oversight of medical and animal use records ( <i>Guide, p 115</i> )						X				
• Procedures established for timely reporting of animal injury, illness, or disease ( <i>Guide, p 114</i> ) <b>[must]</b>						X				
• Procedures established for veterinary assessment, treatment, or euthanasia ( <i>Guide, p 114</i> ) <b>[must]</b>						X				
• Veterinarian is authorized to treat, relieve pain, and/or euthanize ( <i>Guide, p 114</i> ) <b>[must]</b>						X				
2. Animal Procurement and Transportation/Preventive Medicine						A*	M	S	C	NA
• Procedures for lawful animal procurement are in place ( <i>Guide, p 106</i> ) <b>[must]</b>						X				
• Sufficient facilities and expertise are confirmed prior to procurement ( <i>Guide, p 106</i> )						X				
• Procurement is linked to IACUC review and approval ( <i>Guide, p 106</i> )						X				
• Random source dogs and cats are inspected for identification ( <i>Guide, p 106</i> )										X
• Population status of wildlife species is considered prior to procurement ( <i>Guide, p 106</i> )						X				
• Appropriate records are maintained on animal acquisition ( <i>Guide, p 106</i> )						X				
• Animal vendors are evaluated to meet program needs and quality ( <i>Guide, p 106</i> )						X				

• Breeding colonies are based on need and managed to minimize numbers ( <i>Guide, p 107</i> )	X				
• Procedures for compliance with animal transportation regulations, including international requirements, are in place ( <i>Guide, p 107</i> ) [must]	X				
• Transportation is planned to ensure safety, security and minimize risk ( <i>Guide, p 107</i> )	X				
• Movement of animals is planned to minimize transit time and deliveries are planned to ensure receiving personnel are available ( <i>Guide, pp 107- 108</i> )	X				
• Appropriate loading and unloading facilities are available ( <i>Guide, p 109</i> )	X				
• Environment at receiving site is appropriate ( <i>Guide, p 109</i> )	X				
• Policies in place on separation by species, source, and health status ( <i>Guide, pp 109, 111-112</i> )	X				
• Procedures in place for quarantine to include zoonoses prevention ( <i>Guide, p 110</i> )	X				
• Quarantined animals from different shipments are handled separately or physically separated ( <i>Guide, p 110</i> )	X				
• Procedures in place for stabilization/acclimation ( <i>Guide, pp 110-111</i> )	X				
• Policies in place for isolation of sick animals ( <i>Guide, p 112</i> )	X				
• Program is in place for surveillance, diagnosis, treatment and control of disease to include daily observation ( <i>Guide, p 112</i> )	X				
• Diagnostic resources are available for preventive health program ( <i>Guide, p 112</i> )	X				
<b>3. Surgery</b>	<b>A*</b>	<b>M</b>	<b>S</b>	<b>C</b>	<b>NA</b>
• Surgical outcomes are assessed and corrective changes instituted ( <i>Guide, p 115</i> )	X				
• Researchers have appropriate training to ensure good technique ( <i>Guide, p 115</i> ) [must]	X				
• Pre-surgical plans are developed and include veterinary input (e.g., location, supplies, anesthetic and analgesic use, peri-operative care, recordkeeping) ( <i>Guide, p 116</i> )	X				
• Aseptic surgery is conducted in dedicated facilities or spaces, unless exception justified and IACUC approved ( <i>Guide, p 116</i> )	X				
• Surgical procedures including laparoscopic procedures are categorized as major or minor ( <i>Guide, pp 117-118</i> )	X				
• For nonsurvival surgery, the site is clipped, gloves are worn and instruments and area are clean ( <i>Guide, p 118</i> )	X				
• Aseptic technique is followed for survival surgical procedures ( <i>Guide, pp 118-119</i> )	X				
• Effective procedures for sterilizing instruments and monitoring expiration dates on sterile packs are in place ( <i>Guide, p 119</i> )	X				
• Procedures for monitoring surgical anesthesia and analgesia are in place ( <i>Guide, p</i>	X				

<a href="#">119</a> )					
• For aquatic species, skin surfaces are kept moist during surgical procedures ( <i>Guide</i> , <a href="#">p 119</a> )	X				
• Post-operative monitoring and care are provided by trained personnel and documented (e.g., thermoregulation, physiologic function, analgesia, infection, removal of skin closures) ( <i>Guide</i> , <a href="#">pp 119-120</a> )	X				
<b>4. Pain, Distress, Anesthesia and Analgesia</b>	<b>A*</b>	<b>M</b>	<b>S</b>	<b>C</b>	<b>NA</b>
• Guidelines for assessment and categorization of pain, distress and animal wellbeing are provided during training ( <i>Guide</i> , <a href="#">p 121</a> )	X				
• Selection of analgesics and anesthetics is based on professional veterinary judgment ( <i>Guide</i> , <a href="#">p 121</a> )	X				
• Painful procedures are monitored to ensure appropriate analgesic management ( <i>Guide</i> , <a href="#">p 122</a> )	X				
• Nonpharmacologic control of pain is considered as an element of postprocedural care ( <i>Guide</i> , <a href="#">p 122</a> )	X				
• Procedures are in place to assure antinociception before surgery begins ( <i>Guide</i> , <a href="#">p 122</a> ) [must]	X				
• Guidelines for selection and use of analgesics and anesthetics are in place and regularly reviewed and updated ( <i>Guide</i> , <a href="#">p 122</a> )	X				
• Special precautions for the use of paralytics are in place to ensure anesthesia <sup>xiv</sup> ( <i>Guide</i> , <a href="#">p 123</a> )					X
<b>5. Euthanasia</b>	<b>A*</b>	<b>M</b>	<b>S</b>	<b>C</b>	<b>NA</b>
• Methods are consistent with AVMA Guidelines on Euthanasia unless approved by the IACUC ( <i>Guide</i> , <a href="#">p 123</a> )	X				
• Standardized methods are developed and approved by the veterinarian and IACUC that avoid distress and consider animal age and species ( <i>Guide</i> , <a href="#">pp 123-124</a> )	X				
• Training is provided on appropriate methods for each species and considers psychological stress to personnel ( <i>Guide</i> , <a href="#">p 124</a> )	X				
• Procedures and training are in place to ensure death is confirmed ( <i>Guide</i> , <a href="#">p 124</a> ) [must]	X				
<b>6. Drug Storage and Control</b> <sup>NEW</sup>	<b>A*</b>	<b>M</b>	<b>S</b>	<b>C</b>	<b>NA</b>
○ Program complies with federal regulations for human and veterinary drugs( <i>Guide</i> , <a href="#">p 115</a> ) [must]	X				
○ Drug records and storage procedures are reviewed during facility inspections ( <i>Guide</i> , <a href="#">p</a>	X				

<a href="#">115</a> )		
○ Procedures are in place to ensure analgesics and anesthetics are used within expiration date ( <i>Guide</i> , <a href="#">p 122</a> ) <b>[must]</b>	X	
○ Anesthetics and analgesics are acquired, stored, and their use and disposal are recorded legally and safely ( <i>Guide</i> , <a href="#">p 122</a> )	X	

\* **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)

## Spring 2020

Assurance Changes after OLAW site visit on January 29, 2020 has been submitted to OLAW.

### Program Changes Since the Last Semi-annual Program review in October 2019:

- Components of the occupational health and safety program for medical evaluation and preventative medicine for those working with vertebrate animals are in place however, the IACUC requested better monitoring and adherence to the program due to an increased number of gaps in documentation. Additionally, the IACUC recommended moving from a paper-based system to an electronic monitoring system to accommodate more efficient and effective compliance as well as future growth in the use of animals. A letter has been sent to EH&S Senior Director outlining the IACUC's concerns in October 16, 2019. The Program has been revised however a plan for implementation is still needed.
- Guidelines and Policies reviewed and approved by the IACUC:
  - Blood Collection Rodent – Re-review
  - Blood Collection Intracardiac - Re-review
  - Rodent Non-Survival Surgery Guidelines – Re-Review
  - Rodent Survival Surgery Guidelines – Re-review

- Enrichment and Social Housing of Rodents – New
- Euthanasia – Re-review and edited to include new AVMA recommendations
- Animal Observation Only Studies. An evaluation form was approved by the IACUC. The PI will be asked to submit this form for observation only studies evaluation, by the Chair and IACUC office, to determine APF needs.
- IACUC Members who have not yet completed the CITI IACUC Membership training will be reminded to do so, as needed.

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<sup>i</sup> 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.

<sup>ii</sup> 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]

<sup>iii</sup> 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]

<sup>iv</sup> 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]

<sup>v</sup> 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]

<sup>vi</sup> 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]

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<sup>vii</sup> 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]

<sup>viii</sup> 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*]

<sup>ix</sup> 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]

<sup>x</sup> 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..."

<sup>xi</sup> 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]

<sup>xii</sup> 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."

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<sup>xiii</sup> 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].

<sup>xiv</sup> 2.31(d)(iv)(C) - “Procedures that may cause more than momentary or slight pain or distress to the animals will...not include the use of paralytics without anesthesia.”