

September 12, 2019

TO: Pramod Khargonekar, Ph.D.  
Vice Chancellor for Research

FROM: Institutional Animal Care and Use Committee

SUBJECT: Semi-annual Facility Inspection and Program Evaluation Report

Attached are the reports of semiannual facility inspections and the report of the semiannual program evaluation conducted by the Institutional Animal Care and Use Committee (IACUC), as required by PHS Policy on Humane Care and Use of Laboratory Animals, UCI's Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare at NIH, and USDA's Animal Welfare Regulations, 9 CFR Chapter 1, subchapter A, as applicable.

The IACUC inspected the animal facilities on May 7, 8, 10, 13, 15, 21, 29, 30, 31 and June 4, 5, 7 and 14, 2019; using the *Guide* and 9CFR Chapter 1, Parts 1-3. The committee inspected the vivaria and laboratories in [REDACTED]

[REDACTED] A summary of findings is attached.

The laboratory visits are an excellent opportunity to interface with research personnel, review procedures, make recommendations and occasionally hear investigator concerns. In labs where major surgical procedures are performed, site visitors routinely review peri-operative surgical and post-operative monitoring records, making recommendations for improvement where needed. In some cases, the IACUC Administrator or Analysts conduct a spot-review of related protocol files upon return to the office, to ensure that the procedures discussed during the visit are documented in the approved protocol. Campus veterinarians attend most laboratory inspections and provide guidance to researchers as well, both during the inspection and afterward. Staff from Environmental Health and Safety frequently accompany IACUC site visitors and provide separate follow-up when health and safety issues are noted.

The Program Evaluation was performed by members of the IACUC on July 24, 2019. IACUC members based the review on the *Guide for the Care and use of Laboratory Animals* (8<sup>th</sup> edition), and assessed the progress on all recommendations and corrections of past evaluations, setting new goals for completion as necessary. The committee also discussed any programmatic issues stemming from facility inspection findings and recent compliance issues. The Semiannual Program Review Checklist, a template from the

OLAW website, is attached; specific observations, comments and concerns raised in the discussion at the Program Evaluation are included in the appropriate sections of the checklist.

The IACUC reviewed this report and discussed it at its convened meeting on September 12, 2019. A quorum of the committee members voted via email to accept it. No minority reviews were offered.

Enclosures:

1. Facility Inspection Report, Spring 2019
2. List of Locations Inspected – Spring 2019
3. Semiannual Program Review Checklist
4. Email acceptance by quorum of committee members

cc:

[REDACTED]

Director and Attending Veterinarian Lindsell

[REDACTED]

## IACUC Facility Inspection Report - Spring 2019

Inspection Date	Building	Room	Type of Issue	Details & Comments	Deficiency Category	Correction Deadline (Significant Deficiencies only)	Correction Status & Actions	Date Complete
5/7/19			Facilities	Fire sprinkler cap missing; ceiling isn't sealed	M		Informed ULAR facility supervisor.	5/10/19
5/7/19			Expired Material	2 bottles expired Nutrical	M		Left note for lab; [redacted] lab discarded but indicated that the expired Nutrical did not belong to them	5/8/19
5/7/19			Expired Material	Expired Cirpofaoxacin	M		Lab discarded (not used)	5/7/19
5/7/19			Expired Material	Numerous expired items: Vet Bonds, Eye lubricant ointments, "Mapap" liquid, liquid Acetaminophen	M		Left note for lab on pile of expired materials	5/7/19
5/7/19			Multiple (see details)	1) Sink is blocked by wood panel (no other sink in suite), unable to use emergency eye wash; 2) Lamps are clipped onto anesthesia lines	M		Sent email to PI 5-13; Lab confirmed items have been taken care of 5-14	5/14/19
5/7/19			Expired Material	Expired Atropine, antibiotic, eye ointments	M		Left note for lab/ [redacted]	5/7/19
5/8/19			Labels	Feedbin with rodent food, no label	M		Left note for lab to include label with mill/exp date	5/8/19
5/8/19			Equipment	Fume hood overdue for re-certification (label says "Fail", recert date is "ASAP")	M		Emailed EH&S, included lab 5-13 [redacted]	5/13/19
5/8/19			Controlled Drugs	Ketamine/Xylazine mixture stored in fridge unlocked; need separate log to document different dates when mixture is used (logs for origin bottle did not indicate this)	M		Informed PI during inspection, mixture was placed in CS lockbox	5/8/19
5/10/19			Unapproved Activities	Several mouse cages w/o enrichment. Withholding enrichment not on protocol.	M		Emailed lab 5-13/ [redacted]	5/13/19
5/10/19			Controlled Drugs	Several vials labeled ketamine/xylazine left in room on table top. Labels showing expiry date as 1/19	M		Email sent to EHS ([redacted]). IACUC left note and sticker on expired vials.	5/13/19
5/10/19			Animal Care	Mice in several cages labeled "with LAT" that received viral injections (protocol # [redacted] in poor condition (very lethargic, needs attention); Freezer had many bags of dead mice with recent dates (not sure if found dead or euthanized)	S		Vet discussed with lab; lab is aware of high mortality occurring; normal mortality is 40-50% after HSV infection. Mortality is much higher for current experiment (>80%); suspect that titre of virus infection was higher than calculated; batch of virus for some reason might have been more pathogenic, or something with mice made them more susceptible. Lab is investigating. Discussed with lab the need to euthanize mice that are found sick verse letting them die. ULAR management also discussed with husbandry the need to inform vet services when animal mortality is higher than expected.	5/15/19
5/10/19			Equipment	Rabbit restrainer needs cleaning (fur all over)	M		Spoke with lab	5/10/19
5/10/19			Facilities	Hole in wall near change hood, covered with foil	N			
5/10/19			Animal Husbandry	Sentinel rat cage, no cage mate (should be pair-housed)	M		Sentinels were collected and replacements order on 05/13/2019	5/13/19



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Inspection Date	Building	Room	Type of Issue	Details & Comments	Deficiency Category	Correction Deadline (Significant Deficiencies only)	Correction Status & Actions	Date Complete
5/10/19			Facilities	Floor near autoclave is rusty, looks like needs cleaning	M			
5/10/19			Animal Husbandry	Feedbin expired	M			
5/10/19			Equipment	Painted water maze tank, paint at bottom of tank is chipping/flaking off	M		Left note in the water maze tank for the lab	5/10/19
5/10/19			Equipment	Fume hood need recertification? Label states the "re-inspect date" = ASAP; TSS date last certified 2017	M		Lab fixed, fume hood re-certified 5/11	5/11/19
5/13/19			Animal Husbandry	Small feedbin container mill date expirec 3/2018	M		Left note for lab	5/13/19
5/15/19			Logs & Records	Room logs were unclear, lacked details about fish feeding, routine tank system maintenance (when charcoal, filter pads, UV lights are changed, etc.)	M		Spoke with lab 5-13; Emailed, sent sample log template to PI/lab 5-31/	5/31/19
5/15/19			Logs & Records	Missing room log	M		Emailed template to PI/	5/31/19
5/15/19			Equipment	F/Air canister recorded by hour, needs to be weighed.	M		Spoke with lab to record weight of F/Air canister per use	5/15/19
5/21/19			Facilities	Large chips and divots in linoleum floor - potential tripping hazard,	M		Emailed PI 6-6 recommend contacting Facilities Mgmt for repair; Lab replied 6-10 has submitted work order for repair	6/10/19
5/21/19			Protocol	Unfamiliar agents noted in the lab's surgical records (dexamethasone, "chlorproxi...")	M		Email PI, ask for more information	
5/29/19			Multiple (see details)	1) F/Air canister placed upright, which is poor airflow, also no weight recorded; 2) Gas tanks stored in front of emergency eye wash station	M		Emailed lab 5-31; Lab confirmed 5-31/	5/31/19
5/29/19			Labels	Feed bag with no mill/exp date	M		Left note for lab/	5/29/19
5/29/19			Labels	Feed bag with no mill/exp date	M		Informed ULAR	5/29/19
5/29/19				Jugular vein catheter implants protruding out of mice (surgical technique issue?); other than the protrusion the mice did not look distressed	M		Emailed PI/lab 6-6; Lab replied 6-6 clarified that silicone is part of the catheter (pre-implant) and is not applied during surgery; Vet met with lab 6-13; recent batch of catheters had too much silicone which caused the silicone to be exposed; although mice were likely uncomfortable, there were no signs of skin irritation or infection; vet reminded lab manager to ensure lab staff to be more conservative on the amount of silicone applied to catheters; confirmed that the cohort of mice (observed by site visit team) had reached experimental endpoint and were euthanized 6/12	6/13/19
5/29/19			Logs & Records	PI-maintained husbandry room log not signed off by ULAR staff (who checks on weekends)	M		Spoke with ULAR supervisor	5/29/19
5/30/19			Expired Material	Expired PBS	M		Lab will discard	5/30/19

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5/30/19			Expired Material	Lab stated they used expired Ket/Xyl to euthanize animals so as to "not be wasteful"	M		Spoke with lab during inspection, informed them that they must not use expired anesthetics/euthanasia drugs in live animals at any time; Emailed PI 6-6; PI replied, will remind lab staff 6-6/	6/6/19
5/30/19			Logs & Records	Unable to locate 2019 water quality testing logs (found 2018); log on tank cylinder in room was dated 5/10/19 but didn't specify the parameters tested	M		Spoke with lab about water quality testing logs needing parameter details/	5/30/19
5/31/19			Expired Material	Expired Dobutamine, Dopamine	M		Lab will discard	5/31/19
6/4/19			Animal Husbandry	Multiple cages with "Do Not Change" cards are excessively dirty/wet	M		Protocol indicates that ULAR provides all husbandry. Cages should be changed when excessively dirty, regardless of signage. Lab was contacted and cages changed, 06/04/2019.	6/4/19
6/4/19			Animal Husbandry	No husbandry log for June	M		Left note on husbandry log	6/4/19
6/4/19			Expired Material	Scent items (cinnamon, cloves, etc) are expired; should be replaced if they are to be consumed by animals	M		Recommend replacement in email to Pis 6-5; Lab confirmed will replace as suggested 6-10	6/10/19
6/4/19			Recommendations	Cloth chair in procedure room	M		Replace chair or cover with sanitizable surface (email); Lab confirmed will replace as suggested 6-10	6/10/19
6/4/19			Facilities	Autoclave room - debris on floor, ceiling tiles missing	M		Clear out debris and replace ceiling tiles. Leak in area was repaired and tiles replaced	7/1/19
6/7/19			Animal Health	Several cages of weaned mouse pups are too young/very small; at least 1 card DOB 5/20/19 which was weaned too early at 18 days	M		Moistened food pellets provided at bottom of cages, nestlets ripped up to help provide nests, Vet Services to provide nutritional gel, ULAR notified for closer monitoring over the weekend; Emailed PI/lab 6-7; Lab manager replied 6-11 possible miscommunication between lab staff and ULAR; Pups are doing well 6-10; Lab met with ULAR to clear up miscommunication, sent copy of SOP to prevent recurrence (signed by lab members) 6-25	6/25/19
6/7/19			Labels	Feed container with no mill/exp date	M		Left note for lab	6/7/19
6/7/19			Labels	Bag of food with no label	M		Left note on food bag	6/7/19
6/7/19			Expired Material	Expired Neosporin	M		Left sticker on ointment	6/7/19
6/7/19			Equipment	F/Air canister last recorded wt in 2017; re-weighed during inspection and found to be overweight	M		Marked canister as overweight, note for lab to replace	6/7/19
6/7/19			Room	Drain is very filthy, needs to be clean	M		Emailed PI/lab 6-12; Reminder email sent 6/25; Lab cleaned drain 6/26	6/26/19

# IACUC Facility Inspection Report - Spring 2019

Inspection Date	Building	Room	Type of Issue	Details & Comments	Deficiency Category	Correction Deadline (Significant Deficiencies only)	Correction Status & Actions	Date Complete
6/7/19		Room		Floor is dirty with debris, scuff marks (looks like it has not been swept or mopped in a very long time)	M		Emailed PI/lab 6-12; Reminder email sent 6/25; Lab cleaned drain 6/26	6/26/19
6/7/19		Room		Drain is dirty with debris, needs to be cleaned	M		Left note for lab in room	6/7/19
6/14/19		Logs & Records		Fish tank system recently set up but missing room log	M		Sent template to lab/PI	6/18/19



## Site Visit Locations Report - Spring 2019

[REDACTED] - Inspection Date 5/8/19

Room	LR Name	Surgery	Hous>12hrs	Protocol #
		Y	N	
		Y	N	
		Y	N	
		N	N	
		Y	N	
		Y	N	
		N	N	
		N	N	
		N	N	
		Y	N	
		Y	N	
		Y	N	
		N	N	
		N	N	
		N	N	
		Y	Y	
		Y	N	
		Y	N	
		N	N	
		N	N	

[REDACTED] - Inspection Date 5/29/19

[REDACTED]  
All areas, including LR-maintained spaces, inspected

Room	LR Name	Surgery	Hous>12hrs	Protocol #
[REDACTED]	[REDACTED]	N	N	[REDACTED]
		N	N	
		N	N	
[REDACTED]	[REDACTED]	N	N	[REDACTED]
		N	N	

[REDACTED] - Inspection Date 5/29/19

[REDACTED]  
All areas, including LR-maintained spaces, inspected

Room	LR Name	Surgery	Hous>12hrs	Protocol #
		Y		
		N	Y	
		Y	N	
		N	N	
		Y	N	
		N	N	
		N	N	

Room	LR Name	Surgery	Hous>12hrs	Protocol #
		N	N	
		N	N	
		Y	Y	
		N	Y	

- Inspection Date 5/30/19				
Room	LR Name	Surgery	Hous>12hrs	Protocol #
		N	N	
		N	N	
		N	N	
		N	N	
		Y	N	
		Y	N	
		Y	N	
		N	N	
		Y	N	
		N	N	
		N	N	
		Y	N	
		N	N	
		N	Y	
		Y	N	
		Y	N	
		N	N	
		N	N	
		N	N	
		Y	Y	
		N	N	
		Y	N	
		Y	N	
		N	N	



	N	N	
	N	Y	
	N	Y	
	N	N	
	N	Y	
	N	Y	
	N	Y	
	N	N	
	N	Y	
	Y	N	
	N	N	
	Y	N	
	N	Y	
	N	N	

- Inspection Date 6/4/19  
All areas, including LR-maintained spaces, inspected

- Inspection Date 6/14/19				
Room	LR Name	Surgery	Hous>12hrs	Protocol #
		N	N	
		N	N	
		N	N	

- Inspection Date 5/10/19  
All areas, including LR-maintained spaces, inspected

Room	LR Name	Surgery	Hous>12hrs	Protocol #
		N	N	
		N	N	
		N	N	
		Y	N	
		N	N	
		N	N	
		N	N	
		N	Y	
		Y	N	

	N	N	
	N	N	
	Y	Y	
	N	N	
	N	N	
	Y	N	
	Y	Y	
	N	N	
	N	N	
	N	N	
	Y	N	
	N	N	
	N	N	
	Y	N	
	Y	N	
	Y	N	
	N	N	
	Y	N	
	N	N	
	N	N	
	N	Y	
	N	N	
	N	N	

- Inspection Date 5/7/19

All areas, including LR-maintained spaces, inspected

Room	LR Name	Surgery	Hous>12hrs	Protocol #
		N	N	
		N	N	
		N	N	
		N	N	
		Y	N	
		N	N	
		N	N	
		N	N	
		N	Y	
		N	N	

- Inspection Date 5/13/19

All areas, including LR-maintained spaces, inspected

Room	LR Name	Surgery	Hous>12hrs	Protocol #
		N	N	
		Y	N	
		N	Y	
		N	N	
		N	N	
		N	N	
		N	N	
		N	Y	

- Inspection Date 5/8/19

Room	LR Name	Surgery	Hous>12hrs	Protocol #
		N	Y	
		N	Y	
		N	Y	
		N	Y	
		N	N	
		N	N	
		N	N	
		N	N	
		N	Y	
		N	Y	
		N	N	
		N	N	
		N	N	
		N	N	
		N	N	
		N	N	
		N	N	
		Y	N	
		N	N	
		N	N	
		N	N	
		N	N	
		N	N	
		Y	N	
		Y	N	
		N	Y	
		N	Y	
		N	N	
		N	Y	

Room	LR Name	Surgery	Hous>12hrs	Protocol #

	$N$	$N$	
	$N$	$N$	
	$N$	$N$	
	$N$	$N$	

**- Inspection Date 6/7/19**

All areas, including LR-maintained spaces, inspected

All areas, including LR-maintained spaces, inspected

**- Inspection Date 5/31/19**

[illegible]



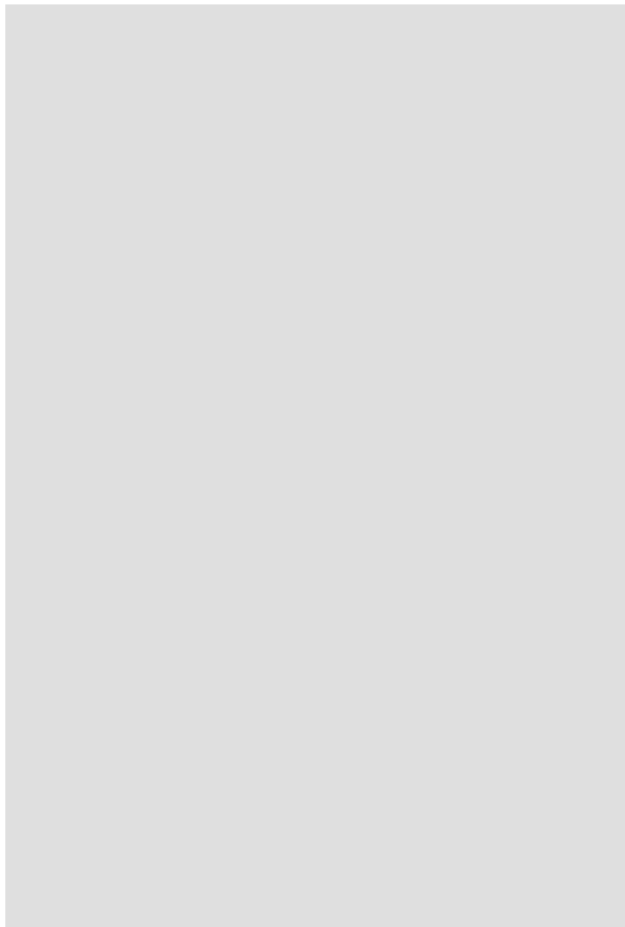
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	Y	N	
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- Inspection Date 5/21/19

ULAR maintained Housing Suite - All areas, including LR-maintained spaces, inspected

ULAR maintained Housing Suite - All areas, including LR-maintained spaces, inspected

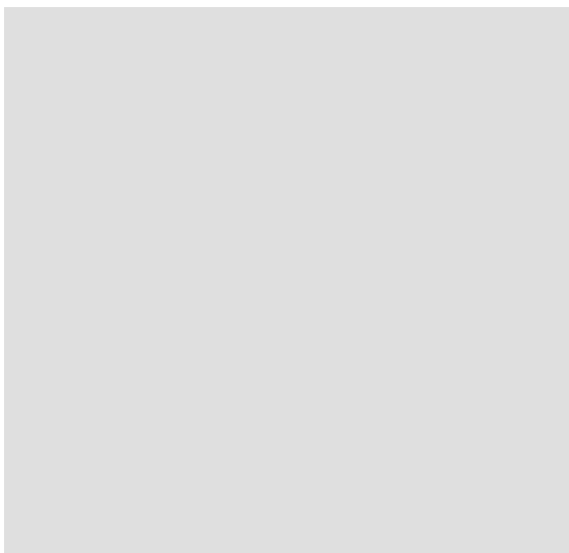
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N	N
Y	N
N	Y
N	N
N	N
N	Y
N	Y
N	N
N	N
N	N
N	N



**- Inspection Date 5/15/19**



N	N
N	N
N	Y
N	N
N	N
N	N
N	N
N	N
N	N
N	N
N	N
N	N
N	N



**- Inspection Date 5/15/19**

Room	LR Name	Surgery	Hous>12hrs	Protocol #
		N	Y	
		N	Y	
		N	Y	
		N	Y	

	N	Y	
	N	Y	
	N	Y	
	N	Y	
	N	Y	
	N	N	
	Y	N	
		Y?	
	Y		
	N	Y	
	N	N	

- Inspection Date 6/14/19

Room	LR Name	Surgery	Hous>12hrs	Protocol #
		N	N	
		N	N	
		N		
		Y	Y	
		N	N	
		Y	N	
		Y	N	

Room	LR Name	Surgery	Hous>12hrs	Protocol #
		N	N	
		N	N	

- Inspection Date 6/14/19

Room	LR Name	Surgery	Hous>12hrs	Protocol #
		N	N	
		N	N	

- Inspection Date 5/13/19

Room	LR Name	Surgery	Hous>12hrs	Protocol #
		N	N	
		N	N	

	N	N	
	N	Y	
	N	N	
	N	N	
	N	N	
	N	N	
	N	N	
	N	N	
	N	Y	
	N	N	
	N	N	
	N	N	

- Inspection Date 6/14/19

All areas, including LR-maintained spaces, inspected

Room	LR Name	Surgery	Hous>12hrs	Protocol #
		N	N	

- Inspection Date 6/5/19

All areas, including LR-maintained spaces, inspected

Room	LR Name	Surgery	Hous>12hrs	Protocol #
		Y	N	
		Y	N	
		Y	N	
		Y	N	
		Y	N	
		Y	N	
		Y	N	
		Y	N	



# I. Semiannual Program Review Checklist <sup>i</sup>

## Institutional Policies and Responsibilities

Date: July 24, 2019

1. Animal Care and Use Program <sup>NEW</sup>	A*	M	S	C	NA
• Responsibility for animal well-being is assumed by all members of the program ( <i>Guide, p 1</i> ) <b>[must]</b>	X				
• IO has authority to allocate needed resources ( <i>Guide, p 13</i> )	X				
• Resources necessary to manage program of veterinary care are provided ( <i>Guide, p 14</i> ) <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, pp 11, 15</i> )	X				
• Program needs are regularly communicated to IO by AV and/or IACUC ( <i>Guide, p 13</i> )	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, p 14</i> ) <b>[must]</b>	X				
• Inter-institutional collaborations are described in formal written agreements ( <i>Guide, p 15</i> )	X				
• Written agreements address responsibilities, animal ownership, and IACUC oversight ( <i>Guide, p 15</i> )	X				

The committee discussed the need for revisions to the policy regarding the use of expired drugs, to include clarification on when it is appropriate to use expired agents.

There was also a discussion regarding the University's acceptance of private-industry funding for research without prior review of potential Research Protections issues. Example: Chinese pharmaceutical company contract accepted by Applied Innovation as an "industry clinical trial".

### ACTION ITEMS:

- New webpage with guidelines for research personnel maintenance of labs and vivarium rooms (general cleanliness, use of cardboard boxes for storage, unpainted wood, rusted surfaces, etc.).
- Guillotine sharpening policy.
- Revisions/clarifications to Expired Drug policy.
- Development of guidelines/SOPs regarding acceptance of private funds for research involving live animals; need better coordination between Office of Research and Applied Innovation.

2. Disaster Planning and Emergency Preparedness <sup>NEW</sup>	A*	M	S	C	NA
• Disaster plans for each facility to include satellite locations are in place ( <i>Guide, p 35, p 75</i> ) <b>[must]</b>	X				
• Plans include provisions for euthanasia ( <i>Guide, p 35</i> ) <b>[must]</b>	X				
• Plans include triage plans to meet institutional and investigators' needs ( <i>Guide, p 35</i> )	X				
• Plans define actions to prevent animal injury or death due to HVAC or other failures ( <i>Guide, p 35</i> )	X				
• Plans describe preservation of critical or irreplaceable animals ( <i>Guide, p 35</i> )	X				
• Plans include essential personnel and their training ( <i>Guide, p 35</i> )	X				
• Animal facility plans are approved by the institution and incorporated into overall response plan ( <i>Guide, p 35</i> )	X				
• Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place ( <i>Guide, p 35</i> )	X				

**ACTION ITEM (Carried over from previous PE):** Create/revise emergency-planning guidance for the IACUC website, especially for PI-maintained animals.

### 3. IACUC

	A*	M	S	C	NA
• Meets as necessary to fulfill responsibilities ( <i>Guide, p 25</i> ) [must]	>				
• IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions ( <i>Guide, p 26</i> ) [must]	>				
• Continuing IACUC oversight after initial protocol approval is in place ( <i>Guide, p 33</i> )	>				
• IACUC evaluates the effectiveness of training programs ( <i>Guide, p 15</i> )	>				

The IACUC always needs additional members, particularly with immunology expertise. Ongoing assistance from the [REDACTED] is needed.

[REDACTED] has expressed an interest in returning to the IACUC ([REDACTED] previously served in 2008-2011). Other suggestions: [REDACTED] and [REDACTED].

**ACTION ITEM:** Continue to work with the [REDACTED] to recruit new members.

### 4. IACUC Protocol Review - Special Considerations

	A*	M	S	C	NA
• 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> )	X				
• For pilot studies, a system to communicate with the IACUC is in place ( <i>Guide, p 28</i> )	X				
• For genetically modified animals, enhanced monitoring and reporting is in place ( <i>Guide, p 28</i> )	X				
• Restraint devices are justified in the animal use protocols ( <i>Guide, p 29</i> ) [must]	X				
• Alternatives to physical restraint are considered ( <i>Guide, p 29</i> )	X				
• Period of restraint is the minimum to meet scientific objectives ( <i>Guide, p 29</i> )	X				
• Training of animals to adapt to restraint is provided ( <i>Guide, p 29</i> )	X				
• Animals that fail to adapt are removed from study ( <i>Guide, p 29</i> )	X				
• Appropriate observation intervals of restrained animals are provided ( <i>Guide, p 29</i> )	X				
• Veterinary care is provided if lesions or illness result from restraint ( <i>Guide, p 30</i> ) [must]	X				
• Explanations of purpose and duration of restraint are provided to study personnel ( <i>Guide, p 30</i> )	X				
• Multiple surgical procedures on a single animal are justified and outcomes evaluated ( <i>Guide, p 30</i> )	X				
• Major versus minor surgical procedures are evaluated on a case-by-case basis ( <i>Guide, p 30</i> )	X				
• Multiple survival procedure justifications in non-regulated species conform to regulated species standards ( <i>Guide, p 30</i> )	X				
• Animals on food/fluid restriction are monitored to ensure nutritional needs are met ( <i>Guide, p 31</i> )	X				
• Body weights for food/fluid restricted animals are recorded at least weekly ( <i>Guide, p 31</i> )	X				
• Daily written records are maintained for food/fluid restricted animals ( <i>Guide, p 31</i> )	X				
• Pharmaceutical grade chemicals are used, when available, for animal-related procedures ( <i>Guide, p 31</i> )	X				
• Non-pharmaceutical grade chemicals are described, justified, and approved by IACUC ( <i>Guide, p 31</i> )	X				
• Investigators conducting field studies know zoonotic diseases, safety issues, laws and regulations applicable in study area ( <i>Guide, p 32</i> )	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				

Literature Searches: A “pain point” in the protocol-approval process – takes considerable committee and administrator time. Process requires guidance, good examples to streamline it.

A brief demonstration of the newly-released RMS User Interface was presented. The sprint that contains the update is currently being tested, will be deployed in Fall 2019.

It was announced that the PubMed user interface is also changing.

### **ACTION ITEMS:**

- Research published information about how best to document consideration of alternatives. Work with IACUC Non-scientific member to develop guidance for the web.
- Publish information/guidance related to the changes in user-interfaces, to ease the transition for end-users.

<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> ) <b>[must]</b>	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				
• 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</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> ) <b>[must]</b>	X				

Members discussed implementation of a Consent Agenda for three-year renewal protocols with minimal changes from the previously-approved version. A description of the process will be included in UCI's PHS Assurance renewal, due for submission to OLAW in October 2019.

**ACTION ITEM:** Develop SOP for Consent Agenda and revise PHS Assurance accordingly.

6. IACUC Training <span style="background-color: yellow;">NEW</span>		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					

Extensive training and reference materials are provided for IACUC members on a secure intranet webpage (WIKI). There is also an extensive User Guide with step-by-step instructions for members in the use of the online protocol system. All new IACUC members are required to complete the CITI modules for committee members. New members are paired with more experienced members as secondary reviewers the first few times they review/present protocols for the committee.

Periodic informal training sessions/discussion of items of interest are held as part of regularly scheduled IACUC meetings as time permits.

**ACTION ITEMS:** None

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.E.</a> )						
○ 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					
○ Institute must promptly advise OLAW of any suspension of an animal activity by the IACUC ( <a href="#">NOT-OD-05-034</a> )	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					



The following is a summary of currently-approved exceptions to the Guide for the Care and Use of Animals (applied throughout the UCI Animal Care Program):

(1) Frequency of cage changing/sanitation:

- Ventilated mouse cages – water bottles<sup>1</sup> and cage bottoms are changed every 2 weeks, wire bars monthly, filtertops every 3 months (autoclaved).
- Static rat cages: Filter tops are changed once every 3 months, and wire bars once a month.

(2) Space requirements:

- Two mouse litters with dams may be housed in single cage, provided the older litter is no more than 5 days older than the younger one.
- 3 rats (400-500 g each) may remain group-housed together if separating them would mean one rat will end up single-housed.

(3) Reduced number of air changes (from 10-15/hour to 6/hour) in housing rooms where cage racks ventilate directly to the outside of the building – this change has resulted in significant energy savings with no appreciable effect on air quality inside cages.

(4) Feeding of special diets/feed: With specific veterinary approval, researchers may use special/medicated diets for up to 9 months past the printed mill date (instead of the usual 6 months), as testing by feed vendors has shown very little nutrient degradation between the 6- and 9-month post-mill-date period.

(5) Humidity levels in feed-storage areas and animal housing rooms occasionally fall outside the recommended range of 30 – 70% published in the Guide; these variations occur most commonly during Santa Ana Wind events when relative humidity can fall below 10%; humidity in Southern California rarely exceeds 70%. UCI HVAC systems do not include humidifiers/dehumidifying equipment; excursions outside the recommended range are infrequent, minimal and of short duration.

Additional project-specific exceptions are described in detail (including strong scientific justification and specific monitoring procedures) in the protocols in which they appear. (E.g. variations in temperature, light cycle, etc.)

<sup>1</sup>Water bottles, particularly in the Lab Products cages, are inside the cage; changing them requires opening the cage and potentially disturbing the animals. It has been noted that the bottles contain enough water to last two weeks.

**ACTION ITEMS:** None

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, p 14</i> ) [must]	X					
• Direct or delegated authority is given to the veterinarian to oversee all aspects of animal care and use ( <i>Guide, p 14</i> ) [must]	X					
• Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol ( <i>Guide, p 5</i> ) [must]	X					
• Veterinarian provides consultation when interventional control is not possible ( <i>Guide, p 5</i> ) [must]	X					
• If part time /consulting veterinarian, visits meet programmatic needs ( <i>Guide, p 14</i> )	X					
• Regular communication occurs between veterinarian and IACUC ( <i>Guide, p 14</i> )	X					

• Veterinarian(s) have experience and training in species used ( <i>Guide, p 15</i> ) [must]	X				
• Veterinarian(s) have experience in facility administration/management ( <i>Guide, p 15</i> )	X				

**ACTION ITEMS:** None

9. Personnel Qualifications and Training	A*	M	S	C	NA
• All personnel are adequately educated, trained, and/or qualified in basic principles of laboratory animal science. Personnel included: [must]					
o Veterinary/other professional staff ( <i>Guide, p 15-16</i> )	X				
o IACUC members ( <i>Guide, p 17</i> )	X				
o Animal care personnel ( <i>Guide, p 16</i> )	X				
o Research investigators, instructors, technicians, trainees, and students ( <i>Guide, pp 16-17</i> )	X				
• Continuing education for program and research staff provided to ensure high quality care and reinforce training ( <i>Guide, pp 16-17</i> )	X				
• Training is available prior to starting animal activity ( <i>Guide, p 17</i> )	X				
• Training is documented ( <i>Guide, p 15</i> )	X				
• Training program content includes: ( <i>Guide, p 17</i> )					
o Methods for reporting concerns ( <i>Guide, p 17</i> )	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 ( <i>Guide, p 17</i> ) <sup>xiii</sup>	X				
o Research/testing methods that minimize numbers necessary to obtain valid results (PHS Policy, <i>IV.A.1.g.</i> )	X				
o Research/testing methods that minimize animal pain or distress (PHS Policy, <i>IV.A.1.g.</i> )	X				
o Use of hazardous agents, including access to OSHA chemical hazard notices where applicable ( <i>Guide, p 20</i> )	X				
o Animal care and use legislation ( <i>Guide, p 17</i> )	X				
o IACUC function ( <i>Guide, p 17</i> )	X				
o Ethics of animal use and Three R's ( <i>Guide, p 17</i> )	X				

**ACTION ITEMS:** None

10. Occupational Health and Safety of Personnel	A*	M	S	C	NA
• 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> )	X				

•					
○ 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

Participation in LAOHP for Facilities Management personnel (noted during 2018 AAALAC site visit): EH&S staff have developed an Information Sheet for Facilities Management and other maintenance staff that occasionally enter animal areas. The Information Sheet will be made available in multiple languages and will provide basic information about animal-related hazards as well as sources for additional information if needed.

EH&S staff perform routine monitoring of scavenging methods for waste anesthetic gas.

**ACTION ITEM:** None

11. Personnel Security <span style="background-color: yellow;">NEW</span>	A*	M	S	C	NA
• Preventive measures in place include pre-employment screening, and physical and IT security ( <i>Guide, p 23</i> )	X				

Sharing of Vivarium Access Cards – need guidance (threats?) for all animal users about not using someone else's keycard. If that's not your face on the card, it will be confiscated!  
Also need guidance about returning vivarium cards when someone leaves the lab.

**ACTION ITEM:** Announcement to all animal users re keycards – (a) don't share and (b) turn them in when you leave.

12. Investigating & Reporting Animal Welfare Concerns <sup>NEW</sup>		A*	M	S	C	NA
• Methods for investigating and reporting animal welfare concerns are established ( <i>Guide, p 23</i> ) <b>[must]</b>	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					

**ACTION ITEM:** None

## Veterinary Care

**Date:** January 25, 2017

1. Clinical Care and Management <sup>NEW</sup>		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:						
◦ Problems with experiments to determine course of treatment in consultation with investigator ( <i>Guide, p 114</i> )	X					
◦ Recurrent or significant health problems with the IACUC and documentation of treatments and outcomes ( <i>Guide, p 114</i> )	X					
◦ 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					

**ACTION ITEM:** None



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> ) [must]	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				

Veterinary staff reported on the use of PCR testing on dust in animal rooms equipped with Techniplast® cage racks; the new process is working well and has substantially reduced the number of sentinel animals needed in vivarium housing rooms.

**ACTION ITEM:** None

3. Surgery	A*	M	S	C	NA
• 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 119</i> )	X				
• For aquatic species, skin surfaces are kept moist during surgical procedures ( <i>Guide, p 119</i> )	X				

<a href="#">119)</a>					
<ul style="list-style-type: none"> <li>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>)</li> </ul>	X				

The “Lone Surgeon” poster has been placed throughout animal facilities in the shared procedure rooms where surgeries occur; the poster, designed by ULAR veterinarians, contains guidance on maintaining a sterile field during surgery.

**ACTION ITEM:** None

4. Pain, Distress, Anesthesia and Analgesia	A*	M	S	C	NA
<ul style="list-style-type: none"> <li>Guidelines for assessment and categorization of pain, distress and animal wellbeing are provided during training (<i>Guide</i>, <a href="#">p 121</a>)</li> </ul>	X				
<ul style="list-style-type: none"> <li>Selection of analgesics and anesthetics is based on professional veterinary judgment (<i>Guide</i>, <a href="#">p 121</a>)</li> </ul>	X				
<ul style="list-style-type: none"> <li>Painful procedures are monitored to ensure appropriate analgesic management (<i>Guide</i>, <a href="#">p 122</a>)</li> </ul>	X				
<ul style="list-style-type: none"> <li>Nonpharmacologic control of pain is considered as an element of postprocedural care (<i>Guide</i>, <a href="#">p 122</a>)</li> </ul>	X				
<ul style="list-style-type: none"> <li>Procedures are in place to assure antinociception before surgery begins (<i>Guide</i>, <a href="#">p 122</a>)</li> </ul>	X				
<ul style="list-style-type: none"> <li>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>)</li> </ul>	X				
<ul style="list-style-type: none"> <li>Special precautions for the use of paralytics are in place to ensure anesthesia<sup>xiv</sup> (<i>Guide</i>, <a href="#">p 123</a>)</li> </ul>	X				

Consistent application of Category E was discussed at length. UCI needs to develop guidance (similar to that of other institutions) that can be applied consistently to delineate pain categories C (minimal/momentary discomfort), D (painful procedures relieved by anesthesia, analgesics or other palliative care) and E (unrelieved pain and/or distress).

Members were informed that sustained-release buprenorphine will soon be available. Researchers will be able to add this agent to existing protocols already approved for regular buprenorphine via minor modification (Accelerated Review/veterinary verification and consultation).

**ACTION ITEM:** IACUC administrative staff to develop guidance on pain categories, bring to future IACUC meeting for committee review.

5. Euthanasia	A*	M	S	C	NA
<ul style="list-style-type: none"> <li>Methods are consistent with AVMA Guidelines on Euthanasia unless approved by the IACUC (<i>Guide</i>, <a href="#">p 123</a>)</li> </ul>	X				
<ul style="list-style-type: none"> <li>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>)</li> </ul>	X				
<ul style="list-style-type: none"> <li>Training is provided on appropriate methods for each species and considers psychological stress to personnel (<i>Guide</i>, <a href="#">p 124</a>)</li> </ul>	X				
<ul style="list-style-type: none"> <li>Procedures and training are in place to ensure death is confirmed (<i>Guide</i>, <a href="#">p 124</a>)</li> </ul>	X				

The American Veterinary Medical Association (AVMA) is in the process of reviewing and revising the Guidelines for Euthanasia. The new guidelines will most likely include changes to the guidance with regard to recommended flow rate. Once the revised Guidelines are released, ULAR will make necessary adjustments to CO2 euthanasia equipment (e.g. flow meters).

**ACTION ITEM:** Update campus policies and SOPs once the changes are finalized and announced.

6. Drug Storage and Control <span style="background-color: yellow;">NEW</span>		A*	M	S	C	NA
• Program complies with federal regulations for human and veterinary drugs( <i>Guide, p 115</i> ) <span style="background-color: cyan;">[must]</span>	X					
• Drug records and storage procedures are reviewed during facility inspections ( <i>Guide, p 115</i> )	X					
• Procedures are in place to ensure analgesics and anesthetics are used within expiration date ( <i>Guide, p 122</i> ) <span style="background-color: cyan;">[must]</span>	X					
• Anesthetics and analgesics are acquired, stored, and their use and disposal are recorded legally and safely ( <i>Guide, p 122</i> )	X					

EH&S staff are doing an excellent job of managing Controlled Substance Use Agreements and multiple DEA licenses for the procurement of controlled substances.

**ACTION ITEM:** None

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- \* **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

<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]

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<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]

<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."

<sup>xiii</sup> 2.32(c) - additional specifications include:

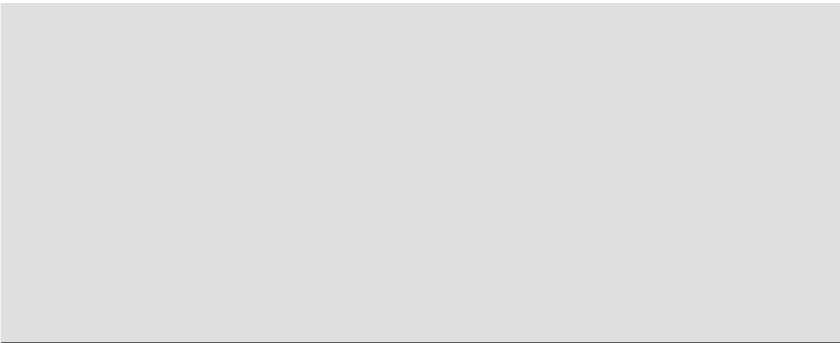
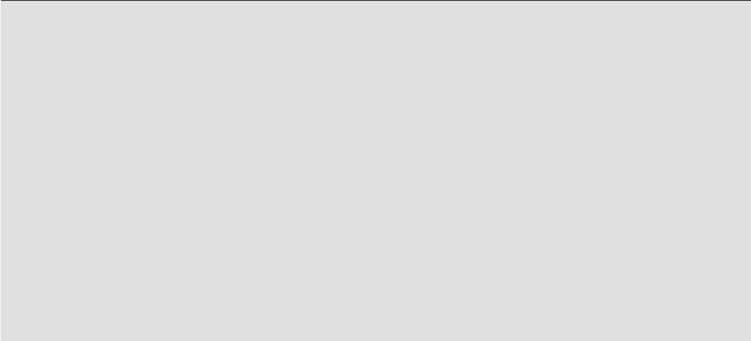
- "proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility"
- "methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility..."
- "utilization of services (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."

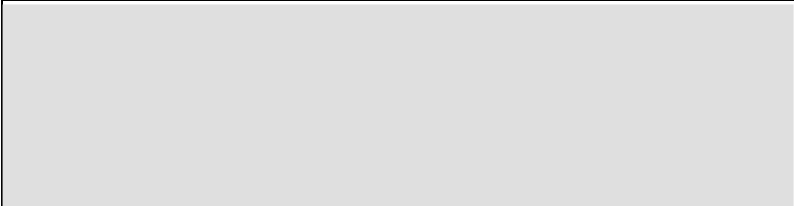
**Spring-Summer 2019 Program Evaluation Report**

Discussed at convened IACUC meeting on September 12, 2019

Reviewed and subsequently approved via email September 16-30, 2019

VOTING MEMBER	SIGNATURE/EMAIL CONCURRENCE
NANCY BURLEY	Tue 9/17/2019 10:14 AM
	
CLAIRE LINDSELL	Tue 9/17/2019 2:55 PM
	

**Alternate Members:**


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