



Office of Animal Care Compliance

September 17, 2020

Richard S. Larson, M.D., Ph.D.
Executive Vice Chancellor,
Vice Chancellor for Research

RE: Fall 2020 MC Semi-Annual Animal Care and Use Program Review, PI Laboratory and Animal Resource Facility Inspections

Mandated by the US Public Health Service, Office of Laboratory Animal Welfare (OLAW) and the Animal Welfare Act and Animal Welfare Regulations (AWA and AWAR), the semi-annual inspections of the [REDACTED] Animal Resource Facilities (ARFs) and PI laboratories were conducted on Wednesday, August 26, 2020. The Main Campus Institutional Animal Care and Use Committee (IACUC) inspectors included: Kevin O'Hair (Attending Veterinarian), Sara Brant (IACUC Chair), and Member #16 (Community Member). One inspector filmed the inspections and the others participated virtually via Zoom. The inspectors were escorted in [REDACTED] Supervisor and in [REDACTED] the inspectors were escorted by the [REDACTED] Supervisor. The Office of Animal Care Compliance (OACC) Sr. Operations Manager and the OACC Compliance Specialist were included on the inspection team. Both the [REDACTED] were impeccably maintained and virtually free from deficiencies other than some infrastructure issues. The supervisors and technicians in both facilities should be highly commended for their outstanding efforts.

Due to recent COVID-19 restrictions, the semi-annual inspections and the program review were completed virtually via Zoom inspections and Zoom Main Campus IACUC meeting on September 17, 2020. This program continues to adhere to provisions of the Guide for the Care and Use of Laboratory Animals, Eighth Edition, the Public Health Service Policy on Humane Care and Use of Laboratory Animals, IV.B. 1-8, and the Animal Welfare Act and Regulations, title 9, chapter 1, subchapter A.

The Committee re-evaluated compliance of the facility infrastructure during this semi-annual inspection. The University committed funding for a new Zebrafish facility project and construction has been completed. Final equipment and tanks were installed by September 4, 2020 and validation of equipment is underway. Once equipment is certified the facility will be operational. Upgrade of the [REDACTED] cage washroom and washer equipment is the last major renovation required to achieve mid-term compliance, research support, and the potential for AAALAC accreditation.

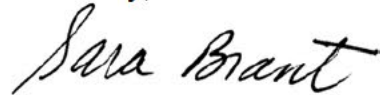
In addition, the [REDACTED] infrastructure has greatly improved over the years with only two remaining midterm equipment replacements that are necessary to optimize animal care, occupational safety, and compliance. The mid-term equipment replacements include an autoclave needed for sterilization of animal cages associated with some research and an aged cage/rack washer unit, which could fail within the next few years.

The committee will continue to work with the Animal Research Advisory Committee (ARAC) and the Office of Research and Economic Development (ORED) to develop time lines and action plans necessary to sustain compliance and achieve the long-term goal of AAALAC International accreditation. Major impediments to accreditation continue to be upgrade of cage wash facilities and addition or upgrade of required functional space in [REDACTED].

A detailed summary of inspection findings is attached. We classify the findings as A = acceptable, M = minor deficiencies, S = significant deficiencies (are or may be a threat to animal health or safety), C = Change in program, and N/A = not applicable.

There were no dissenting or minority views at this time.

Sincerely,



Sara Brant, Ph.D.,
Main Campus IACUC Chair

Semi-annual Inspection of Animal Resource Facilities (ARFs) and PI Laboratories
Main Campus – Virtual Inspections via Zoom - August 26, 2020

Inspectors: AV (Attending Veterinarian), IC (IACUC Chair), Member #16, OCS (OACC Compliance Specialist), OSOM (OACC Senior Operations Manager)

Escorts: [REDACTED]

[REDACTED]						
Inspectors	Deficiencies A, M, S, C, N/A	Location and Lab Function	Deficiency and Plan for Correction and Action (if any)	Responsible Party	Correction 2 Schedule	Date Completed
#16, AV, CHAS OCS, OSOM	C	[REDACTED]	This space is currently under construction to become the new zebrafish facility.	[REDACTED]	N/A	Renovation completed September 4, 2020 and equipment and tank function is being validated
#16, AV, CHAS OCS, OSOM	M	[REDACTED]	Neat and clean overall. 1) The plastic water handling tubes that run from the water supply pipes into the fish tanks contain slight algae growth so they should be monitored and cleaned regularly.	[REDACTED]	N/A	N/A
#16, AV, CHAS OCS, OSOM	A	[REDACTED]	Neat and clean. No deficiencies noted.	[REDACTED]	N/A	N/A
#16, AV, CHAS OCS, OSOM	M	[REDACTED]	Neat and clean. 1) Hood certification has expired.	[REDACTED]	Scheduling has been delayed due to COVID-19 and since they were previously certified they can continue to	Correct as soon as possible.

					be utilized until they are recertified.	
#16, AV, CHAS OCS, OSOM	A		Neat and clean. No deficiencies noted.		N/A	N/A
#16, AV, CHAS OCS, OSOM	M		Neat and clean. 1) PI name and protocol # should be listed on all cage cards. 2) Hood certification has expired.		#1 Correct by September 4. #2 Scheduling has been delayed due to COVID-19 and since they were previously certified they can continue to be utilized until they are recertified.	#1 corrected on 9/4/20
#16, AV, CHAS OCS, OSOM	A		Neat and clean. No deficiencies noted.		N/A	N/A
#16, AV, CHAS OCS, OSOM	A		Very neat and clean. No deficiencies noted.		N/A	N/A
#16, AV, CHAS OCS, OSOM	S		1) The cage wash is a single room with dirty and clean wash processes within the same space. This format increases risks of cross contamination from dirty to clean cages (Ref. NCR 8 th Edition "Guide" page 143 Facilities for sanitizing materials). In addition, the small cage/bottle washer unit lacks required capacity and is antiquated. The washer is 25 years old and many components required for		Correct as soon as funds become available.	Noted and significant since Fall of 2018.

			<p>maintenance/repair are no longer routinely manufactured. The unit currently requires repair but can be used if continuously monitored by staff during cycles. Intermittently the spray rack locks up and if personnel don't immediately stop the cycle further damage to cables and/or clutch drives will occur. If the unit fails, the facility will be required to transport of cages to other washers on campus. Currently there are no Main Campus resources available for containing and safely transporting large numbers of soiled and clean cages/equipment. In addition, large numbers of cages from this facility require sterilization by the ARF for housing of immune deficient mouse models. Exposure of these immune deficient rodents to common environmental microbial agents would compromise research and could result in fatal infections. Sterilization of these cages requires the ARF staff to transfer cages/equipment to the upper floors of [REDACTED]. Transporting cages outside of ARF can result in cross contamination between environment and sterile cages; also scheduling use of the other autoclaves is limited and only clean cages can be autoclaved in these units. The departmental autoclaves are located in student and public areas. Therefore, sterilization of soiled or biohazardous cages in these units is unacceptable due to risks of release of infectious agents</p>			
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			into public areas, not to mention release of noxious odors.			
#16, AV, CHAS OCS, OSOM	A		Neat and clean. No deficiencies noted.		N/A	N/A
#16, AV, CHAS OCS, OSOM	A		Very neat and clean. No deficiencies noted.		N/A	N/A
#16, AV, CHAS OCS, OSOM	A		Very neat and clean. No deficiencies noted.		N/A	N/A
#16, AV, CHAS OCS, OSOM	A		Neat and clean. No deficiencies noted.		N/A	N/A
#16, AV, CHAS OCS, OSOM	M		Neat and clean overall. 1) Wipe down dirty windowsill.		#1 Correct by September 4.	Corrected 8/31/20
#16, AV, CHAS OCS, OSOM	A		Very neat and clean. No deficiencies noted.		N/A	N/A

#16, AV, CHAS OCS, OSOM	A		Neat and clean. No deficiencies noted.		N/A	N/A
#16, AV, CHAS OCS, OSOM	A		Neat and clean. No deficiencies noted.		N/A	N/A
#16, AV, CHAS OCS, OSOM	A		Neat and clean. No deficiencies noted.		N/A	N/A
#16, AV, CHAS OCS, OSOM	A		Neat and clean. No deficiencies noted.		N/A	N/A
#16, AV, CHAS OCS, OSOM	A		Neat and clean. No deficiencies noted.		N/A	N/A
#16, AV, CHAS OCS, OSOM	A		Very neat and clean. No deficiencies noted.		N/A	N/A
#16, AV, CHAS OCS, OSOM	A		Neat and clean. 1) Eyewash tested during inspection. Labs have not been used during the		#2 Correct by September 4.	#2 corrected on 9/4/20

			COVID-19 shutdown but eyewashes are usually tested every 30 days. 2) Hang broom on wall.			
#16, AV, CHAS OCS, OSOM	A		Neat and clean. No deficiencies noted.		N/A	N/A
#16, AV, CHAS OCS, OSOM	A		Neat and clean. No deficiencies noted.		N/A	N/A
#16, AV, CHAS OCS, OSOM	A		Neat and clean. No deficiencies noted.		N/A	N/A
#16, AV, CHAS OCS, OSOM	M		Very neat and clean. 1) Eyewash tested during inspection. Labs have not been used during the COVID-19 shutdown but eyewashes are usually tested every 30 days. 2) Hood certification has expired.		#2 Scheduling has been delayed due to COVID-19 and since they were previously certified they can continue to be utilized until they are recertified.	N/A
#16, AV, CHAS OCS, OSOM	A		Neat and clean. No deficiencies noted.		N/A	N/A
#16, AV, CHAS OCS, OSOM	A		Neat and clean. No deficiencies noted.		N/A	N/A

#16, AV, CHAS OCS, OSOM	A	E	Neat and clean. No deficiencies noted.		N/A	N/A
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A= acceptable, M = minor deficiencies, **S = significant deficiencies (are or may be a threat to animal health or safety)**, and C= change in program, N/A=not applicable.

Semiannual Program Review and Facility Inspection Checklist

About the checklist

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

How to use the checklist

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

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

The checklist consists of the following sections:

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

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

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

Questions or comments?

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

I. Semiannual Program Review Checklist ⁱ

Institutional Policies and Responsibilities

Date: 9-17-2020

1. Animal Care and Use Program	A*	M	S	C	NA
• Responsibility for animal well-being is assumed by all members of the program (Guide, p 1) [must]	✓				
• IO has authority to allocate needed resources (Guide, p 13)	✓				
• Resources necessary to manage program of veterinary care are provided (Guide, p 14) [must]	✓				
• Sufficient resources are available to manage the program, including training of personnel in accord with regulations and the Guide (Guide, pp 11, 15)	✓				
• Program needs are regularly communicated to IO by AV and/or IACUC (Guide, p 13)	✓				
• Responsibilities for daily animal care and facility management are assigned to specific individual(s) when a full-time veterinarian is not available on site (Guide, p 14) [must]	✓				
• Inter-institutional collaborations are described in formal written agreements (Guide, p 15)	✓				
• Written agreements address responsibilities, animal ownership, and IACUC oversight (Guide, p 15)	✓				
2. Disaster Planning and Emergency Preparedness	A*	M	S	C	NA
• Disaster plans for each facility to include satellite locations are in place (Guide, p 35, p 75) [must]	✓				
• Plans include provisions for euthanasia (Guide, p 35) [must]	✓				
• Plans include triage plans to meet institutional and investigators' needs (Guide, p 35)	✓				
• Plans define actions to prevent animal injury or death due to HVAC or other failures (Guide, p 35)	✓				
• Plans describe preservation of critical or irreplaceable animals (Guide, p 35)	✓				
• Plans include essential personnel and their training (Guide, p 35)	✓				
• Animal facility plans are approved by the institution and incorporated into overall response plan (Guide, p 35)	✓				
• Law enforcement and emergency personnel are provided a copy and integration with overall plan is in place (Guide, p 35)	✓				
3. IACUC	A*	M	S	C	NA
• Meets as necessary to fulfill responsibilities (Guide, p 25) [must]	✓				
• IACUC Members named in protocols or with conflicts recuse themselves from protocol decisions (Guide, p 26) [must]	✓				
• Continuing IACUC oversight after initial protocol approval is in place (Guide, p 33)	✓				
• IACUC evaluates the effectiveness of training programs (Guide, p 15)	✓				
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 (Guide, p 27)	✓				
• For pilot studies, a system to communicate with the IACUC is in place (Guide, p 28)	✓				
• For genetically modified animals, enhanced monitoring and reporting is in place (Guide, p 28)	✓				
• Restraint devices are justified in the animal use protocols (Guide, p 29) [must]	✓				
• Alternatives to physical restraint are considered (Guide, p 29)	✓				
• Period of restraint is the minimum to meet scientific objectives (Guide, p 29)	✓				
• Training of animals to adapt to restraint is provided (Guide, p 29)	✓				
• Animals that fail to adapt are removed from study (Guide, p 29)	✓				
• Appropriate observation intervals of restrained animals are provided (Guide, p 29)	✓				

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

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

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

6. IACUC Training A* M S C NA

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

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

• Semiannual report to the IO (PHS Policy, IV.B.)					
○ Submitted to IO every 6 months	✓				
○ Compiles program review and facility inspection(s) results (includes all program and facility deficiencies)	✓				
○ Includes minority IACUC views	✓				
○ Describes IACUC-approved departures from the <i>Guide</i> or PHS Policy and the reasons for each departure ^{vii}	✓				
○ Distinguishes significant from minor deficiencies	✓				
○ Includes a plan and schedule for correction for each deficiency identified ^{viii}	✓				
• Reports to OLAW (PHS Policy, IV.F.)					
○ Annual report to OLAW documents program changes, dates of the semiannual program reviews and facility inspections and includes any minority views	✓				
○ Promptly advises OLAW of serious/ongoing <i>Guide</i> deviations or PHS Policy noncompliance (NOT-OD-05-034)	✓				
○ Institute must promptly advise OLAW of any suspension of an animal activity by the IACUC (NOT-OD-05-034)	✓				
• Reports to U.S. Department of Agriculture (USDA) or Federal funding agency ^{ix}					
○ Annual report to USDA contains required information including all exceptions/exemptions	✓				
○ Reporting mechanism to USDA is in place for IACUC-approved exceptions to the regulations and standards	✓				
○ Reports are filed within 15 days for failures to adhere to timetable for correction of significant deficiencies	✓				
○ Promptly reports suspensions of activities by the IACUC to USDA and any Federal funding agency	✓				
• Records (PHS Policy, IV.E.)					
○ IACUC meeting minutes and semiannual reports to the IO are maintained for 3 years	✓				
○ 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	✓				

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 ^{xi}	✓				
• Veterinary access to all animals is provided (<i>Guide</i> , p 14) [must]	✓				
• Direct or delegated authority is given to the veterinarian to oversee all aspects of animal care and use (<i>Guide</i> , p 14) [must]	✓				
• Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol (<i>Guide</i> , p 5) [must]	✓				
• Veterinarian provides consultation when interventional control is not possible (<i>Guide</i> , p 5) [must]	✓				
• If part time /consulting veterinarian, visits meet programmatic needs (<i>Guide</i> , p 14)					✓
• Regular communication occurs between veterinarian and IACUC (<i>Guide</i> , p 14)	✓				
• Veterinarian(s) have experience and training in species used (<i>Guide</i> , p 15) [must]	✓				
• Veterinarian(s) have experience in facility administration/management (<i>Guide</i> , p 15)	✓				

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]					
○ Veterinary/other professional staff (<i>Guide</i> , p 15-16)	✓				
○ IACUC members (<i>Guide</i> , p 17)	✓				
○ Animal care personnel (<i>Guide</i> , p 16)	✓				
○ Research investigators, instructors, technicians, trainees, and students (<i>Guide</i> , pp 16-17)	✓				
• Continuing education for program and research staff provided to ensure high quality care and reinforce training (<i>Guide</i> , pp 16-17)	✓				
• Training is available prior to starting animal activity (<i>Guide</i> , p 17)	✓				

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

10. Occupational Health and Safety of Personnel

See attachment					

- * **A** = acceptable
M = minor deficiency
S = significant deficiency (is or may be a threat to animal health or safety)
C = change in program (PHS Policy [IV.A.1.a.-i.](#)) (include in semiannual report to IO and in annual report to OLAW)
NA = not applicable

NOTES:

End Notes

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

ⁱⁱ Part 2 Subpart C - Research Facilities

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

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

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

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

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

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

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

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

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

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

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

2.31(d)(1)(iv) - “Procedures that may cause more than momentary or slight pain or distress to the animals will:

- involve in their planning, consultation with the attending veterinarian or his or her designee; [PHS Policy does not specify veterinary consultation]
- not include paralytics without the use of anesthesia;”

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

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

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

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

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

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

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

Reviewed by the IACUC on September 17, 2020.