George M. Pantalos, Ph.D.
Chair, Institutional Animal Care and Use Committee (IACUC)

15 October 2020

Toni M. Ganzel, M.D.
Dean, School of Medicine
Institutional Official, Animal Care and Use Program
University of Louisville
Louisville, KY 40292

Dear Dr. Ganzel:

In compliance with the University of Louisville's (UofL) Assurance with the Public Health Service (PHS) and the "PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy)" and to meet federal requirements (Animal Welfare Act, 9CFR Ch.1), the Institutional Animal Care and Use Committee (IACUC) submits this ***final*** report of the semi-annual self-assessment of the animal care and use program for the Fall of 2020. This report follows and extends the preliminary report forwarded on 17 September 2020. The National Institute of Health (NIH) Guide for the Care and Use of Laboratory Animals ("the Guide") and the USDA's Animal Welfare Regulations were used as the basis for program and facility evaluations.

The IACUC has reviewed relevant University facilities and the overall program for the humane care and use of animals. Facility and laboratory inspections were completed in October 2020. All animal facilities, including vehicles used for transporting animals, were evaluated by the IACUC. Laboratories where animals are maintained for extended periods of time, defined as more than 12 hours for USDA species or more than 24 hours for non-USDA species, and all locations where surgeries occur were also evaluated by the IACUC. ***A table summarizing findings from the inspections not previously reported is attached below.*** A Semi-Annual Program Review Subcommittee (SAPRS) was convened on 9 October 2020; ***the report summarizing their findings is also attached.***

The review revealed that the UofL animal care and use program, including animal housing facilities, continues to meet and exceed federal standards, but identified several areas for improvement. *Many of these have likely already been addressed and resolved.* Recommendations regarding deficiencies and an expected timeline for response are summarized in the attached table and summaries/reports.

Standard operating procedure changes approved by the IACUC in the event of a pandemic were implemented in April 2020, such as extending the cage change interval ventilated rodent caging systems from every two weeks to every three weeks with spot changes, and returned to normal frequency in September 2020. We are pleased to report that we have not had any animal care program personnel contract SARS-CoV-2 and that our excellent program of animal care has continued without interruption.

Animal Care and Use Program

Existing institutional policies were found to be well-established and operating properly. Recommendations for minor revision of some existing policies are included in the attached reports. As you know, the Research Resources Facilities recently underwent a name change to the Comparative Medicine Research Unit (CMRU) to provide a contemporary name that better describes the function of the unit.

Program Management Responsibility

Please note that the 2011 Guide describes additional emphasis on your role as Institutional Official for the animal care and use program. As always, Dr. Sherwood and I would be pleased to meet with you to discuss this role or the findings in this report if you would prefer.

Since the last semi-annual report, the IACUC has approved approximately 23 new projects, 34 three-year renewals, 9 annual reviews, 141 modifications, and 5 tissue proposals. ***IACUC proposal submission and review has remained active during the pandemic, despite obstacles caused by with iRIS system that have significantly delayed the process***. These critical iRIS issues include 6 consecutive days of unavailability in July 2020 due to problems that arose after migration to a cloud hosting solution, as well as current system problems that have halted the review process since 9 October 2020. The Office of Research Integrity is in contact with the vendor to resolve the current issues.

The IACUC continues to provide continuing education to its committee members, which may include articles from relevant literature, CITI case studies, a Policy/Procedure for discussion, and an "Open Discussion" segment of selected *Proposals* to improve consistency in the review process. Other significant discussions and actions include ongoing examination of the enterprise-wide iRIS system and IACUC *Proposal* form. The Office of Research Services has purchased an institutional membership to the Scientists Center for Animal Welfare which is providing a virtual IACUC training course later today. This training course will include presentations and discussions on protocol review methods, IACUC responsibility for quality data in lab animal research, and concepts of compliance. Institutional membership includes access to training videos and free registration to the virtual annual IACUC training course for all IACUC members and a recording will be available for those unable to attend the virtual session in real time.

Personnel Management – Training and Education

Since the last semi-annual report, approximately 260 individuals have taken courses on the CITI Program website including the triennially required "Working with the IACUC" and "Occupational Health and Safety for Animal Handlers" courses.

CMRU Veterinary Staff has continued to offer individualized Level III procedural training sessions, as well as euthanasia training to fulfill researcher personnel needs. These training sessions are offered by request to ensure adherence to University mandates regarding social distancing and room capacity limits. Courses have included general rodent handling, aseptic surgical technique, injection techniques, and other basic procedures. Since the last report, Veterinary Staff has provided over 35 hands-on sessions to Research Personnel.

There have been a number of noteworthy events regarding personnel and their qualifications within the Comparative Medicine Research Unit (CMRU) and IACUC Office. Matthew McCulley, Madison Middleton, and Connor Bollinger passed their ALAT Certification Exams. Stacy Cantrell won the D5 AALAS Distinguished Service Award. Jennifer Kraenzle and Dr. Karen Powell were featured in a *Lab Animal* article about biocontainment.

CMRU personnel continue to provide leadership to laboratory animal science and related associations, including:

- Connor Bolinger (CMRU Husbandry Technician) – Kentucky Branch of the American Association for Laboratory Animal Science (KY-AALAS) President-elect (2021)

- Stacy Cantrell, MBA (IACUC Training Specialist) – KY-AALAS Education Chair; 2022 National AALAS Meeting Local Arrangements Committee Chair
- Tanya Croslin (CMRU Assistant Supervisor) – KY-AALAS President; KY-AALAS Publications
- Tania Griffin (CMRU Assistant Supervisor) – KY-AALAS Secretary; KY-AALAS Hospitality Chair
- Brigitte Foote (CMRU Facilities Manager) – KY-AALAS Treasurer
- Courtney Jenkins (CMRU Unit Business Manager, Sr.) – Serving as UBM Mentor for Department of Orthopedic Surgery
- Maddison Middleton (CMRU Husbandry Technician) – KY-AALAS Board of Directors (2021)
- Joey Mills (CMRU Cagewash Technician) – KY-AALAS Treasurer (2021)
- Mandy Ryan (CMRU Husbandry Supervisor) – KY-AALAS Board of Directors; KY-AALAS Awards Chair
- Mary Proctor, DVM, MS (CMRU Associate Director) – Secretary-Treasurer, Association of Veterans Administration Veterinary Medical Officers
- Tegan Tulloch (IACUC Coordinator) – KY-AALAS Board of Directors
- Leslie Sherwood, DVM (CMRU Director) – AAALACi *Ad Hoc* Consultant

Since the Spring 2020 report, opportunities for CMRU staff education were numerous, despite the inability to hold in-person meeting, due to the Lab Animal Science community's generosity for offering webinars multiple times each week. The Office of Research Services continues to work remotely whenever possible, in accordance with the University's recommendation, but also electronically distributes regular webinar and other announcements to research personnel and CMRU staff for continuing education, professional development, and to combat compassion fatigue.

Last month, the CMRU resumed its monthly general staff meetings virtually through Teams. Stacy Cantrell (IACUC Training Specialist) presented on the importance of AALAS Certification and how to prepare for the Certification Exam. Dr. Karen Powell shared an interesting presentation on field studies at this month's staff meeting.

Environment, Housing, and Management

Animal environment, housing, and management in the CMRU animal facilities, continue to be excellent. Minor issues identified during facility inspections are included in the attached table. All of the CMRU animal facilities are AAALACi accredited. Dr. Leslie Sherwood was awarded an $8M NIH C06 facilities construction grant in September to renovate two floors of the A Tower to provide a centralized vivarium on one floor and dedicated mechanical space to support the vivarium on an additional floor. Architectural and engineering design work is currently underway and the renovation is expected to be completed by October 2024.

Veterinary Care

At the time of inspection, veterinary care was maintained at a very high standard. Minor issues identified during facility inspections are included in the attached table.

Physical Plant

The overall physical condition of most CMRU facilities is good. Physical Plant personnel continue to provide ***outstanding*** support to the UofL animal care and use program through facility maintenance as they are able to, based on their staffing shortage and budget cuts.

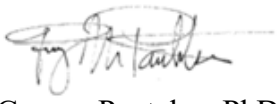
Summary

Principal Investigators and CMRU personnel responsible for the laboratory, facility, and *Proposal* deficiencies identified have been notified. Work orders to Physical Plant have been submitted as needed.

Please note that the IACUC has established a sponsored account for you on our SharePoint site, which contains "Weekly Reports" of protocols that are within the review process (https://cardmaillouisville.sharepoint.com/sites/iacuc/admin/default.aspx). Please use your Outlook user ID and password when signing in to the site. This is done in part to satisfy the PHS requirement regarding the IACUC's responsibility to "notify investigators *and the Institution* [emphasis added] in writing of its decision to approve or withhold approval of those activities related to the care and use of animals."

Please note that exceptions to Guide or USDA standards are included in the SAPRS Report; other study-specific conditions are approved by the IACUC as scientifically justified in portions of approved *Proposals*. The IACUC Office ensured that all recommendations made during the last semi-annual self-assessment were corrected accordingly. As indicated in this report and on behalf of the IACUC, I am pleased to report that the UofL animal care and use program continues to meet high standards. ***There were no minority views to this report***.

Sincerely,



George Pantalos, PhD
IACUC Chair

cc: Leslie Sherwood, DVM, Assistant Vice President, Research Services
Cheri Hildreth, MBA, Director, Department of Environmental Health and Safety
Brigitte Foote, BS, AHT, LATg, CMRU Facilities Manager
Mary Proctor, DVM, MS, Associate Director, Comparative Medicine Research Unit

GP:tnt

Pascale Alard, PhD

Kenneth Palmer, PhD

Geoffrey Clark, PhD

Karen Powell, DVM, MS, PhD

Cynthia Corbitt, PhD

Mary Proctor, DVM, MS, DACLAM

Swati Joshi-Barve, PhD

David Samuelson, PhD

Amanda LeBlanc, PhD

Katie Emmer, DVM, DACLAM
Alternate for Dr. Leslie Sherwood

Ben Lovely, PhD

Kathleen Smith

David Magnuson, PhD

Cheri Hildreth, MBA

Torsten Hopp, PhD

Responsible person(s)	*IACUC#*	*Building*	*Room*	*Findings*	*M inor or S ignificant*	*Deadline for Correction*
Barve, S	20754	[redacted]		Animals are fasted overnight and then until around 3:00 p.m. the following day for "purging" with PEG. The currently approved proposal only indicates "overnight fasting" and does not state that fasting is continued through the PEG purge procedure. A modification must be submitted in iRIS to include this fasting timeline for IACUC review and approval. All fasting must be accurately and completely described in the IACUC proposal and approved by the IACUC before implementation.	S	10/28/2020
Cave, M	18220, 19431			Recently expired bottle of meloxicam present. Expired materials cannot be used without specific IACUC approval. All expired agents must be promptly disposed of or labeled as "EXPIRED - Not for Animal Use" and stored separately. Proper disposal recommended.	S	10/28/2020
Ernst, Ryan, Foote	N/A			Egilmez IACUC 19603 overcrowded cage present. The cage was not marked as overcrowded and no date of birth was marked on the cage card.	S	10/28/2020
Magnuson, D	Multiple			Opened bag of LRS present without an open date recorded. Needle open with cap on it taped to otherside of bag indicating that the same needle may be used repeatedly and possibly for different animals over several days. Needles should not be reused and the same needle should not be used for multiple animals. Inspectors discarded the needle. The LRS should be discarded as well.	S	10/28/2020
Malik, T	N/A			Isoflurane vaporizer overdue for calibration. Equipment should be calibrated and maintained in accordance with manufacturer recommendations. Vaporizer should be labeled "Overdue for Calibration - DO NOT USE" and not used until calibrated.	S	2/8/2021
McCarty, Williamson, Powell	N/A			Famotidine expired 12/2019 present. Expired agents cannot be used without specific IACUC approval. All expired agents must be promptly disposed of or labeled as "EXPIRED - Not for Animal Use" and stored separately. Proper disposal recommended.	M	Corrected.
Hawkins, Foote	N/A			Pest trap from March 2019 found under sink full of dead insects. Traps should be maintained, regularly checked, and replaced in accordance with CMRU SOP.	M	Corrected.

Responsible person(s)	*IACUC#*	*Building*	*Room*	*Findings*	*Minor or Significant*	*Deadline for Correction*
Barve, S	20754	[redacted]		22 cages present with no food and marked with the incorrect card. The green dietary alert card should be placed when animals are fasted. Stating "1 day fasting" is inadequate. The cards must be completed and indicate the fasting start date & time, as well as end date & time.	M	10/28/2020
Bodduluri, H	19605, 20786			Expired betadine present. Expired agents cannot be used without specific IACUC approval. All expired agents stored in the CMRU vivarium must be promptly discarded. Proper disposal recommended.	M	10/28/2020
Cai, J	N/A			Two red biohazard bags present with chemical hazard cages inside. Hazard cards were also not attached to the hazard bags to indicate the specific hazard. All hazardous cages must be bagged using the correct bag type (i.e., chemical hazard bags or biohazard bags). The red hazard card must be removed from the cage and attached to the bag or a new hazard card should be filled out and attached.	M	10/28/2020
Cai, L	Multiple			Two containers of expired glucose test strips. Expired materials cannot be used without specific IACUC approval. All expired agents stored in the vivarium must be promptly discarded. Proper disposal recommended. Note: one box was not labeled with PI name; all materials stored in the animal facilities should be labeled with PI name and IACUC #.	M	10/28/2020
Cave, M	18220, 19431			Diluted solution bottle not properly labeled. All items should be labeled to indicate contents and expiration date.	M	10/28/2020
Clinkenbeard, Foote	N/A			Eye wash station last checked in July 2020. Eye wash stations should be checked monthly and checks should be documented.	M	2/8/2021
Clinkenbeard, Foote	N/A			Indicator strips for autoclaving are often not visible due to clouding or positioning. This should be addressed to ensure that indicator strips can easily be assessed by cage wash staff.	M	2/8/2021
Clinkenbeard, Foote	N/A			Hallway outside of clean cage wash has an autoclaved bag of food with many torn holes in it (presumably to let steam out) that is undated. The food needs to be stored in a sealed container and labeled with an expiration date.	M	10/28/2020
Clinkenbeard, Foote	N/A			ATP sanitation monitoring form only has one entry that says the September reading scored 20 and "failed." No information about retesting or other information provided. Documentation should include what measures are taken when sanitation monitoring has failed.	M	11/4/2020

Responsible person(s)	*IACUC#*	*Building*	*Room*	*Findings*	*Minor or Significant*	*Deadline for Correction*
Clinkenbeard, Foote	N/A	[redacted]		Cage wash floor on dirty side is in need of repair between rack washers and around floor grates. The wall is also damaged and paint is peeling around room above baseboards. These items should be repaired and repainted, as necessary.	M	2/8/2021
Clinkenbeard, Foote	N/A			No sticky pest trap present in room. Traps should be maintained, regularly checked, and replaced in accordance with CMRU SOP.	M	Corrected.
Clinkenbeard, Foote	N/A			License plate is missing from box truck and needs to be located or replaced.	M	11/4/2020
Clinkenbeard, Foote	N/A			Verification of sterilization strips should be recorded daily in the autoclave log. There are many days where no results are documented. Staff should be retrained on documentation in general.	M	11/4/2020
Clinkenbeard, Foote	N/A			Electrical outlet cover is damaged and needs to be repaired/replaced.	M	2/8/2021
Clinkenbeard, Foote	N/A			Freezer needs to be defrosted.	M	11/4/2020
Conklin, D	19534			Laboratory is only cleaning chambers by using warm water and does not have an SOP in place for sanitizing equipment. Warm water is insufficient and an SOP for sanitizing core areas and equipment must be maintained and followed per IACUC Policy (Core Animal Laboratories).	M	11/4/2020
Croslin, Ryan, Foote	N/A			Ceiling is leaking above the sink and needs to be repaired.	M	2/8/2021
Croslin, Ryan, Foote	N/A			Room maintenance log is blank on 9/4/2020. Logs must be filled out completely and consistently in accordance with CMRU SOPs.	M	10/28/2020
Croslin, Ryan, Foote	N/A			Irradiator trays have mouse feces present and need to be cleaned. Trays should be cleaned regularly.	M	11/16/2020
Croslin, Ryan, Foote	N/A			Three containers of unlabeled liquids present. All materials must be labeled to indicate contents and expiration date.	M	10/28/2020
Croslin, Ryan, Foote	N/A			Dilute bleach present with no expiration date. All materials must be labeled to indicate contents and expiration date.	M	10/28/2020
Croslin, Ryan, Foote	N/A			Food present that is past the 6 months from mill date. Per CMRU SOP 3-034, bagged laboratory diets expire 180 days from the milling date. Feed should be checked regularly and disposed of promptly per SOP. Proper disposal recommended.	M	10/28/2020

Responsible person(s)	*IACUC#*	*Building*	*Room*	*Findings*	*Minor or Significant*	*Deadline for Correction*
Croslin, Ryan, Foote	N/A	[redacted]		Expired biological indicators present. Materials should be checked regularly and disposed of promptly when expired. Proper disposal recommended.	M	10/28/2020
Croslin, Ryan, Foote	N/A			Cage cards are on top of rat cages and not attached because the wrong card holders are on cages. Card holders should be replaced so that cards can be attached to and remain with cages.	M	10/28/2020
Croslin, Ryan, Foote	N/A			Induction chamber is dirty and needs to be cleaned.	M	11/4/2020
Croslin, Ryan, Foote	N/A			Water run off/damage has caused a hole in the ceiling and peeling paint. This should be repaired and repainted.	M	2/8/2021
Croslin, Ryan, Foote	N/A			"Do not use" sign is posted on sink with no rationale. The sink should be repaired.	M	2/8/2021
Croslin, Ryan, Foote	N/A			Pass through hood is labeled as broken. The hood should be repaired.	M	2/8/2021
Ding, D	20729			Single housing card present without rationale checked. These cards must be filled out completely in accordance with IACUC policy.	M	10/28/2020
Ernst, Ryan, Foote	N/A			A different system should be used for marking racks to avoid the use of tape and tape residue. Currently racks are marked with autoclave tape.	M	2/8/2021
Feng, W	18378			Ethanol present that is not labeled with a clear expiration date. It only says "9/20/20" but it is unclear what this date means. Items should be labeled to clearly indicate expiration date (e.g., "exp. 9/20/20").	M	10/28/2020
Feng, W	18378			Dietary alert card expired and not completed. These cards must be filled out completely and promptly removed when expired.	M	10/28/2020
Gomes, C	20729			Several single housing cards present without rationale checked. These cards must be filled out completely in accordance with IACUC policy.	M	10/28/2020
Gregg, R	18267, 19535			Medium bag labeled "Gregg lab" with agents in vials with a labeled expiration date of 1/20/2019. Expired materials cannot be used with specific IACUC approval. Expired materials should be disposed of promptly and labeled "EXPIRED - Not for Animal Use" and stored separately. Proper disposal recommended.	M	10/28/2020
Griffin, Ryan, Foote	N/A			Hood is out of date and needs to be re-certified; currently scheduled for October 2020.	M	2/8/2021
Griffin, Ryan, Foote	N/A			No live animal trap present. Traps should be placed and maintained in accordance with CMRU SOP.	M	10/28/2020

Responsible person(s)	*IACUC#*	*Building*	*Room*	*Findings*	*Minor or Significant*	*Deadline for Correction*
Griffin, Ryan, Foote	N/A	[redacted]		No live animal trap present. Traps should be placed and maintained in accordance with CMRU SOP.	M	10/28/2020
Griffin, Ryan, Foote	N/A			Leaky sink faucet needs to be repaired.	M	2/8/2021
Griffin, Ryan, Foote	N/A			Sink is dirty and needs to be cleaned.	M	11/4/2020
Griffin, Ryan, Foote	N/A			Floor is worn and needs to be refinished.	M	2/8/2021
Griffin, Ryan, Foote	N/A			Walls outside of room [redacted] are dirty and need to be cleaned.	M	11/4/2020
Griffin, Ryan, Foote	N/A			The floor needs to be cleaned.	M	11/4/2020
Griffin, Ryan, Foote	N/A			Electrical outlets are coming off of the wall in the hallway outside of room [redacted]. These outlets should be repaired.	M	2/8/2021
Griffin, Ryan, Foote	N/A			Hood is out of date and needs to be re-certified (due 4/2020).	M	2/8/2021
Hawkins, Foote	N/A			Rodent chow with mill date of 3/21/20 in use in room [redacted]. Per CMRU SOP 3-034, bagged laboratory diets expire 180 days from the milling date. Feed should be checked regularly and disposed of promptly per SOP. Proper disposal recommended.	M	10/28/2020
Hawkins, Foote	N/A			Rodent housing rooms have not been sanitized this year according to the husbandry supervisor. Animal housing rooms must be maintained in accordance with CMRU SOP and sanitation should be documented.	M	10/28/2020
Hawkins, Foote	N/A			Rodent room records only incude the current week's information and the inspection team was unable to assess whether the rooms are regularly and properly maintained. Room records should reflect the past 1 month of activity.	M	10/28/2020
Hawkins, Foote	N/A			Light is pulsing and needs to be replaced.	M	11/4/2020
Hawkins, Foote	N/A			Unknown disinfectant present. This should be discarded and replaced with a CMRU-approved disinfectant.	M	10/28/2020

Responsible person(s)	*IACUC#*	*Building*	*Room*	*Findings*	*Minor or Significant*	*Deadline for Correction*
Hawkins, Foote	N/A	[redacted]		Daily tasks are not being completed when room is not in use. This creates a potential for vermin if not maintained regularly and properly. All rooms should be maintained in accordance with CMRU SOP.	M	10/28/2020
Hawkins, Foote	N/A			Floors still need to be refinished.	M	2/8/2021
Hawkins, Foote	N/A			Animals are not being weighed weekly. Animals should be weighed and all weights should be recorded in accorandace with CMRU SOP.	M	10/28/2020
Hawkins, Foote	N/A			Rodent trap is kept on shelf instead of on floor. Traps should be placed and maintained in accordance with CMRU SOP.	M	10/28/2020
Hawkins, Foote	N/A			Rodent trap is kept on shelf instead of on floor. Traps should be placed and maintained in accordance with CMRU SOP.	M	10/28/2020
Hawkins, Foote	N/A			Freezer light is out and needs to be replaced.	M	11/4/2020
Hawkins, Foote	N/A			No insect trap present. Traps should be placed and maintained in accordance with CMRU SOP.	M	10/28/2020
Jala, V	19606			Unlabeled liquid present. All items stored in the vivarium should be labeled to indicate contents, expiration date, PI name, and IACUC #.	M	10/28/2020
Joh, J	16715, 17183			Two containers of cream with written label "0.5905 Fluorouracil" without expiration dates. All items should be labeled to indicate contents and expiration date.	M	10/28/2020
Joh, J	16715, 17183			Unknown substance in eppendorf tube that is not properly labeled. All items should be labeled to indicate contents and expiration date.	M	10/28/2020
Joh, J	16715, 17183			5ml eppendorf tube that is not properly labeled. Has one date of "2/15/19" but unclear what this date means. Unknown white powder not in solution. All items should be labeled to indicate contents and expiration date (e.g., "exp. 2/15/19").	M	10/28/2020
Kakar, S	N/A			Expired artificial tears (exp. 6/2020) present. Expired materials cannot be used without specific IACUC approval. All expired agents stored in the vivarium must be promptly discarded. Proper disposal recommended.	M	10/28/2020
Kraenzle, J	N/A			Green line rat cages are very cloudy and have reduced visibility. These opaque cages should be surplused/discarded and replaced if necessary.	M	2/8/2021
Kraenzle, J	N/A			Several Allentown ferret cages have very cloudy glass and reduced visibility. These opaque cages should be cleaned or replaced.	M	2/8/2021

Responsible person(s)	*IACUC#*	*Building*	*Room*	*Findings*	*M inor or S ignificant*	*Deadline for Correction*
LeBlanc, A	Multiple	[redacted]		Conical tube sitting out on counter with gauze in a clear liquid. Secondary container not labeled with name of substance or expiration date. All agents must be labeled to indicate contents and expiration.	M	10/28/2020
Magnuson, D	Multiple			Cages are not being identified or labeled in accordance with the Guide and IACUC policy. One rat cage present without a cage card - yellow post-it note "13", no yellow cellophane to indicate recent surgery, no surgery date on cage #239755 or cage "13". All cages must have cage cards at all times in accordance with the Guide. Cage cards should be labeled to indicate that a surgery occurred and date of surgery; a yellow cellophane card should be placed on cages immediately after surgery and removed when staples/sutures/wound clips are removed.	M	10/28/2020
Magnuson, D	Multiple			Diluted gentamicin and antisedan present with no expiration date. All containers and agents must be labeled to indicate contents and expiration dates. Proper disposal recommended.	M	10/28/2020
Magnuson, D	Multiple			No initials on post-op surgery log of the individual completing the log.	M	10/28/2020
Matoba, N	Multiple			Expired PBS (exp. 1/2019) present. Expired materials cannot be used without specific IACUC approval. All expired agents stored in the vivarium must be promptly discarded. Proper disposal recommended.	M	10/28/2020
McCarty, Powell, Williamson	N/A			An unlabeled bag of rodent chow present inside a cabinet drawer. All feed should be labeled to indicate contents and expiration date. Proper disposal recommended.	M	10/28/2020
McCarty, Powell, Williamson	N/A			Daily cleaning log for RRC/CMS support areas has some days not checked (8/24, 8/26, 8/31). Rooms should be cleaned in accordance with CMRU SOP and logs updated to reflect cleaning.	M	10/28/2020
McCarty, Powell, Williamson	N/A			Light out that needs to be replaced.	M	2/8/2021
McCarty, Powell, Williamson	N/A			Air vent covering is dirty and needs to be cleaned.	M	11/4/2020

Responsible person(s)	*IACUC#*	*Building*	*Room*	*Findings*	*Minor or Significant*	*Deadline for Correction*
McCarty, Powell, Williamson	N/A	[redacted]		Fluid pump is dirty and needs to be cleaned.	M	11/4/2020
McCarty, Powell, Williamson	N/A			Incomplete autoclave sterilization verification logs. These logs must be filled out completely and consistently in accordance with SOPs.	M	10/28/2020
McCarty, Powell, Williamson	N/A			Incomplete ETO sterilization verification logs. These logs must be filled out completely and consistently in accordance with SOPs.	M	10/28/2020
McCarty, Powell, Williamson	N/A			Incomplete support area maintenance logs. Rooms must be maintained and logs must be filled out completely and consistently in accordance with SOPs.	M	10/28/2020
McCarty, Powell, Williamson	N/A			Light out in the equipment storage room that needs to be replaced.	M	11/4/2020
Miller, D	N/A			Boxes locked and unavailable to inspect; CMRU husbandry supervisor emailed laboratory in advance of inspections to request that boxes be unlocked during inspections. All items stored in the CMRU vivaria must be unlocked and made available during IACUC inspections.	M	10/28/2020
Miller, D	18386			Unknown blue chemical in eppendorf tube that is not properly labeled. All items should be labeled to indicate contents and expiration date.	M	10/28/2020
Ng, C	18304, 18306			No documentation of floor sanitation on room sanitation log. Floors appear dirty and should be cleaned. Representative indicated room is sanitized every 2 weeks, but not every time between animals and people. The room should be sanitized between use by animals and people. Sanitation should be documented. See attached CMRU SOP 3-35 and maintenance log.	M	11/4/2020
Palmer, K	N/A			Boxes locked and unavailable to inspect; CMRU husbandry supervisor emailed laboratory in advance of inspections to request that boxes be unlocked during inspections. All items stored in the CMRU vivaria must be unlocked and made available during IACUC inspections.	M	10/28/2020
Physical Plant	N/A			Eye wash station last checked in April 2020. Eye wash stations should be checked monthly and checks should be documented.	M	2/8/2021

Responsible person(s)	*IACUC#*	*Building*	*Room*	*Findings*	*Minor or Significant*	*Deadline for Correction*
Physical Plant	N/A	[redacted]		Eye wash station last checked in April 2020. Eye wash stations should be checked monthly and checks should be documented.	M	2/8/2021
Physical Plant	N/A			Eye wash station last checked in April 2020. Eye wash stations should be checked monthly and checks should be documented.	M	2/8/2021
Physical Plant	N/A			Eye wash station hasn't been checked since April 2020. Eye wash stations should be checked monthly and checks should be documented.	M	2/8/2021
Physical Plant	N/A			Eye wash station last checked in April 2020. Eye wash stations should be checked monthly and checks should be documented.	M	2/8/2021
Physical Plant	N/A			Eye wash station last checked in February 2020. Eye wash stations should be checked monthly and checks should be documented. Rooms [redacted]	M	2/8/2021
Physical Plant	N/A			Emergency shower and eye wash stations last checked in February 2020. Eye wash stations and showers should be checked monthly and checks should be documented. Rooms [redacted]	M	2/8/2021
Physical Plant	N/A			Eye wash station last checked in February 2020. Eye wash stations should be checked monthly and checks should be documented. Rooms [redacted]	M	2/8/2021
Physical Plant	N/A			Eye wash stations have no card indicating routine checks. Eye wash stations should be checked monthly and checks should be documented on cards.	M	2/8/2021
Physical Plant	N/A			Water leak from pipe on floor in dirty cage wash. Pipes should be assessed for leaks and repaired.	M	2/8/2021
Powell, Williamson, McCarty	N/A			Suture with a needle sitting out on the table in the operating room while the room is not in use. Sharps should be discarded immediately or stored safely in accordance with DEHS guidelines.	M	10/28/2020
Rodent Vet Staf	N/A			Fridge includes items that look expired or unused; it's unclear because some are not properly labeled. All materials should be labeled to include contents and expiration date. Expired materials should be discarded promptly. Proper disposal recommended.	M	10/28/2020
McCarty, Powell	N/A			Expired hand soap (7/20/20) and peroxigard spray bottle in the room. Agents should be checked regularly and discarded promptly when expired. Proper disposal recommended.	M	Corrected.
McCarty, Powell	N/A			Carbo-lime expired 8/2020. Agents should be checked regularly and discarded promptly when expired. Proper disposal recommended.	M	Corrected.

Responsible person(s)	*IACUC#*	*Building*	*Room*	*Findings*	*Minor or Significant*	*Deadline for Correction*
Samuelson, D	20715	[redacted]		Expired substances present: sterile blades exp. 10/2017 and PBS expired 5/30/2019. Expired agents cannot be used without specific IACUC approval. All expired agents must be promptly disposed of or labeled as "EXPIRED - Not for Animal Use" and stored separately. Proper disposal recommended.	M	10/28/2020
Samuelson, D	20715			Bottle of 80% EtOH labeled as "mixed 5/15/2018" but no indication of expiration. All substances should be labeled to indicate contents and expiration date. This substance should be discarded.	M	10/28/2020
Samuelson, D	20715			Expired tattoo ink (small container in plastic bag) present (exp. 8/28/20). Expired agents cannot be used without specific IACUC approval. All expired agents must be promptly disposed of or labeled as "EXPIRED - Not for Animal Use" and stored separately. Proper disposal recommended.	M	10/28/2020
Sen, U	N/A			Single housing card present without rationale checked. These cards must be filled out completely in accordance with IACUC policy.	M	10/28/2020
Severson, W	20743			No SASP posted associated with infected animals. SASPs should be posted and removed as stated on the SASP and in accordance with DEHS requirements.	M	10/28/2020
Siskind	19568			Dietary alert card not completed. These cards must be filled out completely.	M	10/28/2020
Slaughter, Koenig	Multiple			Large amount of expired materials present that need to be discarded. Agents should be checked regularly and discarded promptly when expired. Proper disposal recommended. Only the amount of materials needed for active experiments should be stored in this area.	M	10/28/2020
Unknown - will be sent to CMRU for correction	N/A			Used water bottles partly filled stored in PI drawer with no name. Proper disposal recommended.	M	10/28/2020
Unknown - will be sent to CMRU for correction	N/A			Lab supplies stored in an unlabeled eppendorff tube in the fridge outside of room [redacted]. All items stored in the vivarium should be labeled to indicate contents, expiration date, PI name, and IACUC #.	M	10/28/2020

Responsible person(s)	*IACUC#*	*Building*	*Room*	*Findings*	*Minor or Significant*	*Deadline for Correction*
Unknown - will be sent to CPM Director and CMRU for correction	N/A	[redacted]		Expired materials present: 24g IV catheters (exp. 4/2015) and 60 ml syringes (exp. 7/2018). Expired materials cannot be used without prior IACUC approval. Proper disposal recommended. Note: none of these items were appropriately labeled with PI names. All laboratory materials in the vivarium should be labeled with the PI's name and IACUC number.	M	10/28/2020
Unknown - will be sent to CPM Director and CMRU for correction	N/A			PBS present without any dates and an unknown liquid stored in a 50ml conical tube present. All items must be labeled to indicate contents and expiration date. Proper disposal recommended. Note: none of these items were appropriately labeled with PI names. All laboratory materials in the vivarium should be labeled with the PI's name and IACUC number.	M	10/28/2020
Unknown - will forward to CMRU for assistance with correction.	N/A			Drawer locked and unavailable to inspect; CMRU husbandry emailed all users of this room in advance of inspections to request that drawers be unlocked during inspections. All drawers in the CMRU vivaria must be unlocked and made available during IACUC inspections.	M	10/28/2020
Warawa, J	N/A			Box marked "Warawa lab" containing expired triple antibiotic (exp. 7/2019) and insulin syringes (exp. 11/2016). Expired materials cannot be used without specific IACUC approval. All expired agents stored in the vivarium must be promptly discarded. Proper disposal recommended.	M	10/28/2020
Warawa, J	Multiple			Box marked "Warawa lab" containing a pipette box with insulin syringes with no expiration date. All items should be labeled to indicate contents and expiration date.	M	10/28/2020
Wright, Clinkenbeard, Foote	N/A			Out of date pest monitoring (sticky traps). Traps should be placed and maintained in accordance with CMRU SOP.	M	10/28/2020
Zhou, H	N/A			Sterile PBS that is not properly labeled to include an expiration date. All items should be labeled to indicate contents and expiration date.	M	10/28/2020

George M. Pantalos, Ph.D.
Chair
Institutional Animal Care and Use Committee (IACUC)

17 September 2020

Toni M. Ganzel, M.D., M.B.A.
Dean, School of Medicine
Institutional Official, Animal Care and Use Program
University of Louisville
Louisville, KY 40292

Dear Dr. Ganzel:

In compliance with the University of Louisville's (UofL) Assurance with the Public Health Service (PHS) and the "PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy)" and to meet federal requirements (Animal Welfare Act, 9CFR Ch.1), the Institutional Animal Care and Use Committee (IACUC) submits this ***preliminary*** report of the semi-annual self-assessment of the animal care and use program for the Fall of 2020. *Given the increase in size and complexity of our program, the IACUC has found it increasingly difficult to complete the self-assessment and submit its findings to you within the timeframe recommended by regulatory authorities (30 days); therefore, you will receive a preliminary report summarizing findings to date followed by a final report once completed.*

Attached please find a table summarizing the laboratory inspections conducted between 27 August and 10 September 2020. These findings were discussed at the IACUC meeting of 17 September 2020; the Committee approved the designation of departures and the response deadline depicted in the table. The Committee has now added a list of commendations for laboratories. Letters will be produced and forwarded to the responsible individuals listed in the table requesting an explanation of the findings and description of their resolution by the deadline listed, as well as noting any commendations acknowledged by the IACUC. ***There were no minority views to this report***.

The IACUC anticipates review and approval of a final semi-annual report at its meeting of 15 October 2020. Please know that the IACUC would be pleased to discuss these findings with you in person if it would be of assistance.

Sincerely,

George Pantalos, PhD
IACUC Chair

University of Louisville, Louisville, KY 40292
P: 52.852.7307 **F**:502-852.7943

Pascale Alard, PhD

Kenneth Palmer, PhD

Geoffrey Clark, PhD

Karen Powell, DVM, MS, PhD

Cynthia Corbitt, PhD

Mary Proctor, DVM, MS, DACLAM

Swati Joshi-Barve, PhD

David Samuelson, PhD

Amanda LeBlanc, PhD

Leslie Sherwood, DVM

Ben Lovely, PhD

Kathleen Smith

David Magnuson, PhD

Sucheta Telang, MD

Cheri Hildreth, MBA

Torsten Hopp, PhD

University of Louisville

Animal Care and Use Program
Semi-Annual Program Review Subcommittee
Report and Recommendations
Fall 2020

As part of the Semi-Annual Self-Assessment (SASA) process, Semi-Annual Program Review Subcommittee (SAPRS), composed of Drs. Joshi-Barve, Samuelson and Sherwood convened on 9 October 2020 at 1:00 PM.

A. Summary of Final Fall 2020 Laboratory and Facility Inspection Findings – (Attachment A)

The Subcommittee reviewed the final report of semiannual inspection findings for the Fall 2020 SASAs. The Subcommittee identified no issues of programmatic concern.

Recommended Deadline for Action: ***Not Applicable.***

B. Update for Action Items from the Spring 2020 SAPRS Report (Attachment B)

One minor deficiency identified during the Spring 2020 semiannual inspections is overdue for correction by Physical Plant due to the pandemic. The floors in RRC pod 4 were identified as stained and needing to be refinished, with a deadline of September 30, 2020. The Subcommittee has asked the IACUC Office to follow-up with the CMRU Facility Manager in regard to the finding to ensure completion.

[redacted]

C. IACUC Policies and Procedures

The Subcommittee reviewed the following IACUC policies and recommended the below revisions:

1. Research Involving Collaborating Institutions **(Attachment C)**
   [redacted]
2. Reporting and Investigating Animal Welfare Concerns **(Attachments D through F)** – *None.*
3. Individual Risk Assessment and Medical Surveillance **(Attachments G and H)**
   [redacted]
4. Hazardous Agent Review and Approval **(Attachment I)**
   [redacted]
5. Acclimation Periods for Newly-Received Animals **(Attachment J)** – *None.*

[redacted]

D. Selected RRF Standard Operating Procedures

The Subcommittee will review of the following new or revised policy/procedures:

1. RRF SOP Index **(Attachment K)**
2. SOP 3-005-01, Care and Management of Cats **(Attachment L)**
   [redacted]
3. SOP 3-029-00, Sanitation of Post-Op Housing Room and Stationary Stanchions **(Attach. M)**

[redacted]

4. SOP 3-031-00, Effective and Humane Identification Via Toe Tattoo in Rodents **(Attach. N & O)**
[redacted]

E. IACUC-Approved Departures to *Guide* or USDA Standards (Attachment P)

The subcommittee noted that the attachment summarized IACUC-approved departures to *Guide* or USDA standards as well as some "unusual" deviations. Not included in the list were numerous *Proposals* for which the use of non-pharmaceutical-grade drugs, expired or non-sterile materials have been reviewed and approved by the IACUC. All instances of temporary or permanent individual housing, prolonged restraint, or multiple survival surgeries may not be included; justification can be found in the individual *Proposals*.

The Office of Research Services flagged three IACUC *Proposals* (18398, 18231, and 18265) approved for food and/or fluid regulation that do not clearly state the weighing frequency of animals. The *Guide* states that animals should be weighed at least frequently and that deviations from this must be scientifically justified. The Office of Research Services is updating the IACUC *Proposal* form to better capture this required information. The subcommittee recommends [redacted]

The Office of Research Services also identified inconsistencies regarding temporary versus permanent prolonged restraint criteria. The subcommittee recommended [redacted]

F. Semi-Annual Program Review Checklist (Attachment Q)

The assessment was assisted by use of the revised "Semiannual Program Review Checklist" provided by OLAW (v3/8/2012).

G. VA Spring 2020 Semi-Annual Report

The Subcommittee reviewed the Robley Rex VA Medical Center's (VA) Spring 2020 Semi-Annual Self-Review. The VA's report was submitted to the UofL in accordance with Memorandum of Understanding between the VA and University of Louisville in regard to their collaboration on the use of animals in research, teaching, and testing. The Subcommittee found no items of concern.

Recommended Deadline for Correction: ***N/A***

H. Animal Welfare Assurance

The Subcommittee reviewed the "University of Louisville (A3586-01) Animal Welfare Assurance in accordance with the PHS Policy for Humane Care and Use of Animals," approved on 2 February 2018, as well as the Annual Reports for 2018 and 2019. The Subcommittee found no items of

concern. All programmatic changes have been adequately described in annual reports to OLAW.

Recommended Deadline for Correction: ***N/A***

University of Louisville
Institutional Animal Care and Use Committee
Policies and Procedures

Reporting and Investigating Animal Welfare Concerns

Policy: The humane care and use of animals is of paramount importance to the University of Louisville. Individuals who may have specific concerns about animal care and treatment are strongly encouraged to report their observations of suspected deficiencies to the Institutional Animal Care and Use Committee (IACUC), Comparative Medicine Research Unit (CMRU), Institutional Official (Executive Vice President for Health Affairs), or Institutional Compliance Office. Individuals generating a report of concern shall not be discriminated against or be subject to any reprisal for generating the report. Individuals who desire anonymity may be certain that the IACUC will handle a report of concern in confidence to the extent permitted by law. Signs alerting personnel to their opportunity to report concerns should be posted in all animal use areas, including laboratories where live animals are used.

Rationale: Ethical mores, federal regulations, and accreditation standards dictate that perceived deficiencies and other concerns are investigated thoroughly. The Guide (2011) states, "Safeguarding animal welfare is the responsibility of every individual associated with the Program." Institutional methods for reporting and investigating animal welfare concerns are mandatory. USDA Regulations place the responsibility for review and investigation with the Institutional Official and IACUC.

Procedures, Guidelines, and Exceptions:

1. ***Reporting Procedures:***
   a. Concerns regarding misconduct associated with the care and treatment of animals may be reported verbally or in writing to the IACUC chairperson, any committee member, or a CMRU veterinarian. A current roster of IACUC members may be obtained from the IACUC (502-852-7307).
   b. Concerns may also be reported to any of the CMRU management staff, including veterinarians, the facility manager, and facility supervisors or assistant supervisors (502-852-5268).
   c. Concerns may also be submitted via the University's Compliance Helpline (877-852-1167) or the "Compliance Helpline Reporting" option on ULINK under the External Links section of the Faculty/Staff tab (http://louisville.edu/compliance/helpline).
   d. Mechanisms for reporting concerns will be posted in prominent locations in the facility and applicable website(s) with instructions on how to report the concern and to whom.

2. ***Reports should be as specific as possible****, i.e.,* date, time, species involved, animal/project identification number and the names of the UofL personnel involved, if possible.

3. ***IACUC Response to Reports of Animal Welfare Concerns:***
   a. The receipt of a written or verbal report of animal concern by the IACUC will be immediately brought to the attention of the Associate Vice President for Research Services and/or the IACUC Chairperson, unless a conflict of interest exists. This(ese) individual(s) will select (an) additional committee member(s) to constitute a Subcommittee to investigate and, where concerns are

Original Approval: 16 August 2007
Revised: 20 November 2014; 15 January 2015
Latest Approval: 16 November 2017

substantiated, recommend the correction of the reported concern. Alternates for these individuals may also be selected such that the investigative subcommittee consists of three IACUC members, including one veterinarian. All IACUC members will be notified of a pending Subcommittee meeting, except where a potential conflict of interest exists.

b. At the next regularly scheduled IACUC meeting, the Subcommittee will describe the reported concern and the corrective action that has been taken or recommended. Reports and corrective actions will conform to all applicable University policies.
c. If, and when, a letter reporting a deficiency is forwarded to an outside regulatory agency (*i.e.*, OLAW, AAALAC), funding agency (through the Office of Grants and Contracts), or in other instances where notification seems appropriate as determined by the committee**,** a letter will also be forwarded to the department chair affiliated with the project in question. IACUC and subcommittee members will remain honor-bound to respect report confidentiality.

Original Approval: 16 August 2007
Revised: 20 November 2014; 15 January 2015
Latest Approval: 16 November 2017

NOTICE

This notice is posted in accordance with IACUC Policy:

Reporting and Investigating Animal Welfare Concerns

http://louisville.edu/research/iacuc/policies.html

The humane care and use of animals is of paramount importance to the University of Louisville. Individuals who may have specific concerns about animal care and treatment are encouraged to report their concerns either verbally or in writing to one of the following:

1. Institutional Animal Care and Use Committee (IACUC)

Written reports may be addressed to the Chair or other committee members, including CMRU Veterinary Faculty at: *IACUC Office, Medical-Dental Research Building, Room 015, Health Sciences Center, University of Louisville, Louisville, KY 40292.* A current roster of IACUC members may be obtained from the Office of Research Services (502-852-7307).

2. Comparative Medicine Research Unit (CMRU)

Concerns may be reported to any of the CMRU management staff, including veterinarians, Facility Manager, and Facility Supervisors or Assistant Supervisors. Written reports may be addressed as above or: Office of Research Services, *Medical-Dental Research Building, Room 012, Health Sciences Center, University of Louisville, Louisville, KY 40292, 502-852-5268.*

3. Institutional Official (Vice President for Academic Medical Affairs)

Written reports may be addressed as either of the above or: Office of the Vice President for Academic Medical Affairs, *Abell Administration Center, 323 E. Chestnut St., Louisville, KY 40202, 502-852-1499.*

4. Institutional Compliance Office

Concerns may also be submitted via the University's Compliance Hotline (877-852-1167) or the "Compliance Hotline Reporting" option on ULINK under the External Links section of the Faculty/Staff tab (http://louisville.edu/compliance/hotline).

Reports should be as specific as possible, *i.e.*, date, time, species involved, animal/project identification number and the names of the UofL personnel involved, if possible.

Individuals generating a report of concern s*hall not be discriminated against or be subject to any reprisal for generating the report.* Individuals who desire anonymity may be certain that the IACUC will handle a report of concern *in confidence to the extent permitted by law.*

NOTICE

Original Approval: 16 August 2007
Last Approval: 16 November 2017

通 告

此通告是按照实验动物维护管理及使用委员会规章规定

保护实验动物福利汇报及调查

http://louisville.edu/research/iacuc/policies.html

对实验动物的人道管理及使用是路易维尔大学的首要关注.个人如有任何有关实验动物使用及处理不当情况,可将他们的关注以口头或以书信文件与以下部门联络

1. *Institutional Animal Care and Use Committee (IACUC)*
实验动物维护管理及使用委员会*(IACUC)*

书信报告请寄委员会主席或委员,包括实验动物中心兽医人员:实验动物维护管理及使用委员办事处*IACUC Office, Medical-Dental Research Building, Room 015, Health Sciences Center, University of Louisville, Louisville, KY 40292.* 现职 IACUC 委员名单请向研究服务办事处索取.请电 502-852-6899.

2. *Comparative Medicine Research Unit (CMRU)*
实验动物比较医学研究中心*(CMRU)*

关心事项报告可接洽 任何实验动物比较医学研究中心的管理人员,包括兽医,中心经理和中心主管或主管助理. 书面报告请寄以上地址或: 研究服务办事处 Office of Research Services, *Medical-Dental Research Building, Room 012, Health Sciences Center, University of Louisville, Louisville, KY 40292, 502-852-5268.*

3. *Institutional Official (Vice President for Academic Medical Affairs)*
大学行政官员(学术医学事务副总裁)

书面报告也可寄至: Office of the Vice President for Academic Medical Affairs, Abell Administration Center, 323 E. Chestnut St., Louisville, KY 40202, 502-852-1499.

4. *Institutional Compliance Office* 机构规章监督办事处

关心事项也可提交于大学规章监督热线 (877-852-1167) 或上路大网站"路大规章监督提报热线", 在线 ULINK 选项,请选 Faculty/Staff 选项卡 (http://louisville.edu/compliance/hotline).

报告必须明确,日期,时间,涉及物种,动物/项目标识号,如可能请告知路大涉及人员之姓名.

报告者将不会被歧视或遭受打击报复.匿名报告者可确定
实验动物维护管理及使用委员会将在法律容许的范围内处理匿名报告.

通 告

修正: 2020年8月25日

采用: 2012年2月16日

University of Louisville
Institutional Animal Care and Use Committee
Policies and Procedures

Acclimation Periods for Newly-Received Animals

Policy: The UofL Institutional Animal Care and Use Committee (IACUC) requires an acclimation and stabilization period for all animals arriving at the university prior to experimental manipulations. All newly received laboratory animals must be held for a minimum number of days (depending on the species and intended use) without any experimental manipulation for acclimation, observation, and potential treatment. Acclimation periods do not include the day of arrival/shipment. Exceptions to this policy must be requested in an IACUC proposal describing the rationale for the exception, and must be approved by the IACUC.

Rationale: The *Guide* states, "Regardless of whether the animals are quarantined, newly received animals should be given a period for physiologic, behavioral, and nutritional acclimation before their use." The *Agricultural Guide* states, "Newly received animals require a period of acclimation. Acclimation refers to a stabilization period, before animal use, which permits physiological and behavioral adaptation to the new environment." Transportation causes stress in animals and subsequently changes an animal's physiological status during transportation and for some period thereafter. Stress associated with transportation has been shown to have changes on the cardiovascular, endocrine, immune, central nervous and reproductive systems. These effects can adversely impact research results. New housing conditions, changes in social groupings, new feed, and new care staff are all additional stressors to newly received laboratory animals. An acclimation period allows animals time to adapt to a new environment, for physiological changes to stabilize, and promotes both animal welfare and reproducible experimental results. Based on current literature, the UofL IACUC has adopted the following guidelines.

Procedures, Guidelines, and Exceptions:

1. ***Definitions:***
   a. **Acclimation:** The period during which newly arrived research animals are allowed to recover from the physiologic and psychological stress of shipping prior to being used in research, teaching, or testing proposals. Nutritional stabilization and adjustments to new surroundings, feed, light/dark cycles, cage/pen mates, and personnel also take place during this time period.

   b. **Quarantine:** The separation of newly received animals from those already in the facility until the health and possibly the microbial status of the newly received animals have been determined with the goal of minimizing the chance for introduction of pathogens into an established colony. Quarantine periods for animals may vary in duration based on the species, the source and health status of the incoming animals, and regulatory requirements. This policy does not address quarantine and researchers should contact a Comparative Medicine Research Unit veterinarian for further information on quarantine requirements for specific situations.

Original Approval: 18 July 2013
Revised: 17 September 2015
Last Approval: 17 May 2018

2. ***Rodent Species***
    a. Researchers are advised to consider the effect that shipping stress may have on experimental data based on individual research needs.
    b. For euthanasia and tissue harvest only, animals may be used the day of arrival.
    c. For all other uses, a minimum of 72 hours is required; this includes following internal transfer between buildings requiring outdoor routes during temperature extremes.

3. ***Non-Rodent Species (dogs, cats, ferrets, rabbits, birds, pigs, calves, goats, sheep)***
    a. For euthanasia and tissue harvest only, animals may be used the day of arrival.
    b. To reduce the chance of stress-induced disease, including anesthetic death, a minimum of 1 week (7 days) is recommended for non-survival surgery or other procedures; however, a minimum of 3 days (72 hours) is required.
    c. A minimum of 1 week (7 days) is required for survival surgery or long-term experiments.

References:

1. Aguila HN, Pakes SP, Lai WC, Lu YS. The effect of transportation stress on splenic natural killer cell activity in C57Bl/6J mice. Lab Anim Sci, 1988; 38:148-151.
2. Bean-Knudsen DE, Wagner JE. Effect of shipping stress on clinicopathologic function in F344/N rats. Am J Vet Res, 1987; 48(2):306-8.
3. Breinekova K, Svoboda M, Smutna M, Vorlova L. Markers of acute stress in pigs. Physiol. Res. 2007; 56: 323-9.
4. Capdevila S, *et al*. Acclimatization of rats after ground transportation to a new animal facility. Lab Anim, 2007;41(2);255-61.
5. Everitt JI, Schapiro SJ. The art and science of introducing animals to the research environment. ILAR J. 2006; 47(4):281-2.
6. FASS (Federation of Animal Science Societies) 2010. Guide for the Care and Use of Agricultural Animals in Agricultural Research and Testing.
7. Hicks TA, *et al*. Behavioural, endocrine, immune, and performance measures for pigs exposed to acute stress. J Anim Sci, 1998; 76(2);474-83.
8. Hodgson PD, *et al*. Effect of stress on viral–bacterial synergy in bovine respiratory disease: novel mechanisms to regulate inflammation. Comp Funct Genom, 2005; 6:244-250.
9. Kannan G, Terrill TH, Kouakou B, Gazal OS, Gelaye S, Amoah EA, Samake S. Transportation of goats: effects on physiological stress responses and live weight loss. J Anim Sci, 2000; 78:1450-1457.
10. Knowles TG, *et al.* Effects on cattle of transportation by road for up to 31 hours. Vet Rec, 1999; 145:575-82.
11. Landi MS, Kreider JW, Lang CM, Bullock LP. Effects of shipping on the immune function in mice. Am J Vet Res.,1982; 43:1654-57.
12. McGlone JJ, Salak JL, Lumpkin EA, Nicholson RI, Gibson M, Norman RL. Shipping stress and social status effects on pig performance, plasma cortisol, natural killer cell activity, and leukocyte numbers. J Anim Sci, 1993; 71:888-96.
13. Murata H, *et al.* Influence of truck transportation of calves on their cellular immune function. Nippon Juigaku Zasshi, 1985; 47:823-27.
14. NRC (National Research Council) 2011. Guide for the Care and Use of Laboratory Animals.
15. NRC (National Research Council) 2006. Guidelines for the Humane Transportation of Research Animals.
16. Obernier JA, Baldwin RL. Establishing an appropriate period of acclimatization following transportation of laboratory animals. ILAR J. 2006; 47(4):364-9.
17. Rowland RT, *et al.* Transportation or noise is associated with tolerance to myocardial ischemia and reperfusion injury. J Surg Res, 2000; 89:7-12.
18. Tuli J, *et al.* Stress measurements in mice after transportation. Lab Anim, 1995;2 9:132-8.

Original Approval: 18 July 2013
Revised: 17 September 2015
Last Approval: 17 May 2018

UofL

Research Resource Facilities

SOP Index

Origination and Revisions (O: Date, R: Date) **In Progress** **Retired** **Open Spot** ***Revision in Progress**

1-000-00 **RESERVED FOR FUTURE USE**

2-000-00 **DEPARTMENTAL POLICIES**

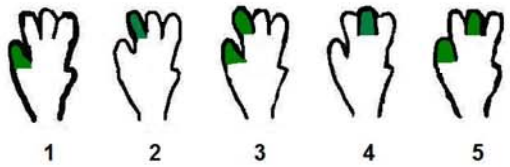
- **2-001-05** Development, Implementation and Maintenance of Standard Operating Procedures *(O: 10/1/00, R01: 8/23/09, R02: 10/29/10, R03: 7/18/12, R04: 3/13/13, R05: 3/15/19)*
- **2-002-02** *PPE Requirements (O: 1/26/18, R01:3/15/19, R02:3/9/20)*
- **2-003-00** Research Resources Facility Vehicles *(O: 12/21/15)*
- **2-004-01** *Entry Order (O: 1/26/18, R01:3/13/19)*
- **2-005-03** Facility Access *(O: 12/20/10, R01: 2/2/15, R02: 3/20/18, R03: 8/21/19)*
- **2-006-03*** USDA and FDA Inspections *(O: 9/17/09, R01: 10/29/10, R02: 9/18/12, R03:2/2/16)*
- **2-007-02** SOP Fonts and Formatting *(O: 8/23/09, R01: 10/29/10, R02: 7/18/12)*
- **2-008-02** RRF SOP Template *(O: 8/23/09, R01: 10/29/10, R02: 7/18/12)*
- **2-009-03*** Uniforms *(O: 9/17/09, R01: 3/13/13, R02: 12/21/15, R03: 9/11/20)*
- **2-010-01*** Storage and Retention of Records *(O: 9/18/12, R01: 6/24/13)*
- **2-011-00** RRF Forms Catalog: Development, Revision, and Use (O: 6/1/15)
- **2-012-00** IACUC Proposal Expiration (O: 3/9/20)

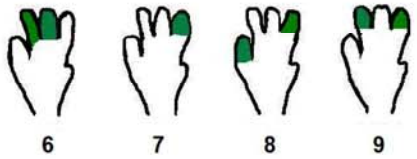
3-000-00 **ANIMAL CARE**

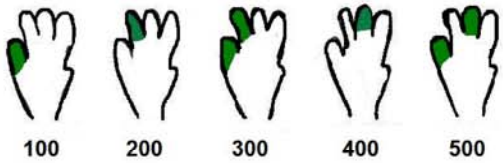
- **3-001-00** Husbandry of Frogs *(Retired 3/10/10)*
- **3-002-02** Defining, Reporting, and Correcting Common Rodent Housing Issues *(O: 1/25/01, R01: 3/10/10, R02: 6/10/20)*
- **3-003-00*** Procedures for Altering Normal Feeding Schedules of Large Animals
- **3-004-00** Care and Management of Tree Shrews *(Retired 5/9/19)*
- **3-005-01** Care and Management of Cats *(O: 7/21/08, R01:3/20/18)*
- **3-006-01** Husbandry of Rabbits *(O: 7/15/08, R01: 6/20/19)*
- ***3-007-00*** *OPEN*
- **3-008-02** Care and Management of Mice and Rats *(O: 12/21/10, R01: 9/24/19, R02: 2/14/20)*
- **3-009-02** Care and Management of Dogs *(O: 3/19/09, R01: 10/2/09, R02: 2/28/19)*
- ***3-010-00*** *OPEN*
- **3-011-03** Care and Management of Swine *(O: 3/10/10, R01: 6/16/15, R02:1/17/19, R03: 2/19/20)*
- ***3-012-00*** *OPEN*
- ***3-013-00*** *OPEN*
- ***3-014-00*** *OPEN*
- **3-015-00*** Receiving Animals from Non-Commercial Sources
- **3-016-03** Care and Management of Sheep & Goats *(Retired 10/5/15)*
- **3-017-00*** Internal Transfer *(O: 12/21/15)*
- **3-018-00*** Care and Management of Guinea Pig
- **3-019-00** Rodents Found in Cagewash and Escaped Rodents (O: 8/6/19)
- ***3-020-00*** *OPEN*
- ***3-021-00*** *OPEN*

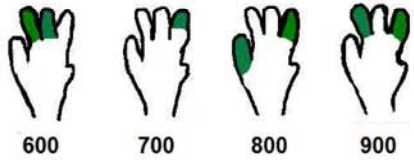
5-008-00 Use of the Drager X-am 5100 Single Gas Hydrogen Peroxide Sensor *(O: 4/9/20)*
5-009-01* Record Keeping in Cagewash *(O: 8/5/09, R01: 6/19/13)*
5-010-00* Use of the Edstrom Model BFS-675 Bottle Filling Station
5-011-00 *OPEN*
5-012-01* Cage Washer Room Maintenance *(O: 6/19/13, R01: 10/21/13)*
5-013-00 *OPEN*
5-014-00 *OPEN*
5-015-00* Movement of Clean and Dirty Cages – HSC and LSB
5-016-00 *OPEN*
5-017-01* Washer Sanitization Assurance/New Washer Validation *(O: 5/17/03, R01: 3-13-13)*
5-018-00* General Procedure for Using Ventilated Racks
5-019-00 Operation of the GSE Large Animal Floor Scale *(O: 7/30/09)*
5-020-00 Operation and Maintenance of Britz-Heidbrink HEPA Filtered Transport Carts *(O: 11/15/07)*
5-021-00 Operation of the Beacon Medaes Lifeline Medical Gas Manifolds *(O: 1/21/08)*
5-022-00* Operation of the Allegany Palletweigher Scale *(O: 7/23/08)*
5-023-00 Use of the Getinge™ Model 7128 Steam Sterilizer-RRF/RRC Surgical Facility *(O: 7/23/08, Retired 9/24/19)*
5-024-00 Use of the Idexx VetTest™ Blood Chemistry Analyzer *(O: 5/22/08, Retired 12/16/10)*
5-025-00 Use of the Idexx VetStat™ Electrolyte and Blood Gas Analyzer *(O: 5/23/08, Retired 12/16/10)*
5-026-00 Use of the BT™ Hydraulic Lift Jack *(O: 7/23/08)*
5-027-00* Operation of the Basil and Girton Cage Washers *(O: 7/23/09)*
5-028-00 Use of the Control Company™ Min/Max Thermometer/Hygrometer *(O: 7/23/08)*
5-029-00 Use of the Castle Model 513973 ST Steam Sterilizer *(O: 12/11/08, Retired: 9/17/19)*
5-030-00* Standard Operation, Sterilization Verification & Maintenance of RRF Sterilizers
5-031-02 Use of the Bair Hugger Temperature Management Unit *(O: 8/8/09, R01: 10/5/09, R02: 5/16/18)*
5-032-01 Use of the DRE Trax Model 100 Monitor *(O: 8/4/09, R01: 10/5/09, Retired 11/19/13)*
5-033-01 Use of the Aquasonic® Model 750T Ultrasonic Cleaner *(O: 1/23/10, R01: 12/10/10)*
5-034-01 Operation of the Vetland EX3000 Anesthesia System *(O: 2/23/10, R01: 2/25/11)*
5-035-00* Use of the Hygenia SystemSURE ATP Reader *(O: 12/1/10)*
5-036-00 Use of the Physio-Control Defibrillator *(O: 3/1/11)*
5-037-00 Operation of the Mettler Toledo Excellence XS Precision Balance *(O: 3/1/11)*
5-038-00 Operation of the Extech Light Meter *(O: 9/18/12)*
5-039-00 Use and Maintenance of the Cardell MAX-12HD Vital Signs Monitor *(O: 11/9/12)*
5-040-00* Use of the [redacted] Getinge 2100 Series Washers
5-041-00 *OPEN*
5-042-00 *OPEN*
5-043-00* Use of the [redacted] 2 Model 2236 Tunnel Washer *(O: 5/05/14)*

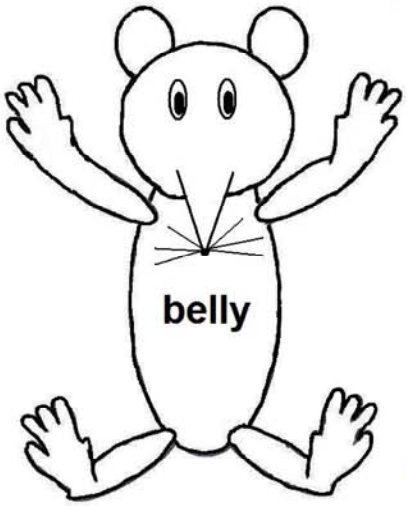
TOE TATTOO GUIDE

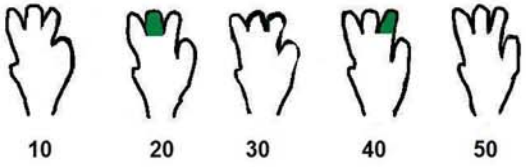


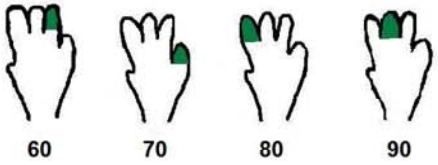




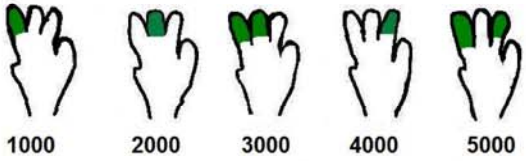


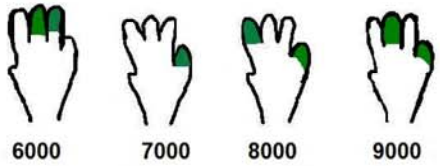






Do Not Use "Thumbs"!





RRF Exceptions

PI Name	IACUC	Species	Exception to Standards	Rationale	Duration	Additional Review
RRF	NA	Mice	Cage changing intervals (up to 3 weeks); wire bar lids changing (every other cage change)	To ensure animal welfare in the event of significant animal care staff absenteeism during a pandemic, ventilated cage change frequency may be extended to 3-weeks with spot changing as necessary, and wire bar lids in rodent cages may be changed every other cage change.	During a pandemic, in accordance with the RRF Pandemic Plan and under the direction of the Asst. Vice President for Research Services/Director RRF	March 2020 IACUC Minutes; Spring 2020 SAPRs
RRF / Bodduluri	20725 (Under Review)	Mice	Gnotobiotic and Germ Free Cage Sanitation Intervals (up to annually)	Animals in germ-free isolators will have bedding changed weekly, but will not have new cages or cage components changed while germ-free up to once/year. Rigorous testing is done to ensure that their environment is sterile, in which case disinfection is unnecessary.	NA	November 2019 IACUC Minutes; Spring 2020 SAPRs
RRF	NA	Mice and rats	IVCS Rack Sanitation	Semi-annually at HSC; Annually at RBL.	NA	Spring 2020 SAPRs*
RRF	NA	Mice and rats	IVCS Rack Sanitation (Lab Products; B2V)	Based on data presented by the RRF, Lab-Products IVCS racks may be sanitized at intervals of 12 months, unless a "flooding" event occurs (in which the drinking water back-flows into the air supply plenum).	NA	Spring 2020 SAPRs; March 2017 IACUC Minutes*
RRF	NA	Mouse	Cage Sanitation Intervals (up to 2 weeks)	Individually-housed mice in IVCS may be changed bi-weekly. Sanitation interval for female mice with litters may be extended beyond weekly to prevent disturbing very young neonates.	NA	Spring 2020 SAPRs*

*Note that the above "global exceptions" were also presented in the 2018-2019 AAALAC Program Description and reviewed during the Site Visit.

RRF Exceptions

PI Name	IACUC	Species	Exception to Standards	Rationale	Duration	Additional Review
RRF	NA	Guinea pig	Housing - Primary Enclosures	The interior space unimpeded by suspended lofts and feeders/water bottles holders (approximately 9.5" x 13", or 123.5 in^2) is adequate for 2 guinea pigs up to 350 g (120 in^2) but less than the minimum floor space requirement or over 350 g (202 in^2). Acknowledging that enclosures providing social housing is more important than minimal space standards, the lofts enhance environmental enrichment, and the use of individually-ventilated caging allows significantly greater biological security, the use of these cages meets the definition of "innovative primary enclosures that do not precisely meet the space requirements…, but that do provide guinea pigs or hamsters with a sufficient volume of space and the opportunity to express species-typical behavior."	NA	Spring 2020 SAPRs; March 2014 IACUC Minutes*
RRF	NA	Mice and rats	Co-housing multiple species	Rats and mice may be co-housed in B2-070 within the B2V because of the need to isolate animals exposed to biological hazards and extremely limited space in the vivarium. All animals are housed in Individually-Ventilated Cage systems and mouse and rat rackss are placed on opposite sides of the room, effectively limiting the potential for olfactory or visual contact.	NA	Spring 2020 SAPRS*

*Note that the above "global exceptions" were also presented in the 2018-2019 AAALAC Program Description and reviewed during the Site Visit.

RRF Exceptions

PI Name	IACUC	Species	Exception to Standards	Rationale	Duration	Additional Review
RRF	NA	Rabbits	Social Housing	Agression is a significant issue with group-housed males, often resulting in serious injury. Young males will be pair- or group-housed until sexual maturity (14-16 weeks of age for rabbits), at which point animals will be permanently individually-housed unless housed with (a) female(s) for breeding. Females will be pair- or group-housed upon arrival. Females demonstrating social incompatibility will be at least temporarily individually-housed. If an adequate number of additional females is available and the study is anticipated to progress longer than 2 additional weeks, at least three attempts at identifying a suitable cage mate will be completed before assigning the female to permanent individual housing. When individual housing is deemed necessary, rabbits will be provided every opportunity for social experience as possible. This will include additional environmental enrichment as well as visual and olfactory contact with conspecifics	NA	Spring 2020 SAPRS; May 2015 Minutes*

*Note that the above "global exceptions" were also presented in the 2018-19 AAALAC Program Description and reviewed during the Site Visit.

IACUC#	PI	Species	Exception	EXCEPTION_DESCRIPTION	DURATION
18197	Lovely, Charles B	Zebrafish	Exemption from Environmental Enrichment	During the fin clip procedure fish have to be housed individually to confirm genetic identity. The fish will be placed in static, fish safe tupperware that has air holes to provide gas exchange. Due to the short duration of time in the static tupperware no enrichment will be added. Fin Clipping is a stressful event and changing their environment can add to that stress.	Fish will be in Fin clip tupperware an average of 1.5 days. Maximum time would will be 4 days. In the rare exception that they have to remain in tupperware longer than 4 days, this fish will be moved to a small system tanks and placed on the system for feeding and cleaning purposes.
18231	King, Suzanne N	Rat	Exemption from Environmental Enrichment	Observation chamber or plexiglass box will be used to permit voluntary feeding/breathing while standing unrestrained in a confined space. Chamber and boxes meet the required size of 60-70 square inches. Chamber/box used for lick and swallow studies is ~7.5" wide by ~12" long with height of ~7"; the box used for respiratory testing is about 3x larger. To acclimate animals to the observation chamber or plexiglass box that will be used during fluoroscopy, lick, or respiratory tests, containers may be left overnight in the animals' home cage. Enrichment material may be removed to encourage animals to explore and sleep in the chamber.	overnight period; 5-10x during study period
19654	O'Toole, Timothy E	Mouse	Exemption from Environmental Enrichment	No enrichment is provided for urine collection lest material absorb urine or otherwise interfere with collection. No enrichment is provided for metabolic cages to avoid interference with the physical activity sensors sensors	up to 24hr for urine collection, up to 72 hours for metabolic cages
20757	Magnuson, David S	Rat	Exemption from Environmental Enrichment	This is only applicable if the animals are in the small 21.5x19cm cages and cage space restriction is needed based on the approved protocol for these conditions. Otherwise all animals will be provided appropriate enrichment.	Up to 8 weeks unless otherwise stated in individual protocols.
20764	Carll, Alex P	Mouse	Exemption from Environmental Enrichment	No enrichment is provided for urine collection lest material absorb urine or otherwise interfere with collection. No enrichment is provided for metabolic cages to avoid interference with the physical activity sensors sensors	up to 24hr for urine collection, up to 72 hours for metabolic cages
20781	Conklin, Daniel	Mouse	Exemption from Environmental Enrichment	No enrichment is provided for urine collection lest material absorb urine or otherwise interfere with collection. No enrichment is provided for metabolic cages to avoid interference with the physical activity sensors sensors	up to 3 days

Food/Fluid Regulation

IACU	PI	Species	Justification	Extent	Length	Monitoring	Assurance
18253	Baba, Shahid P	Mouse	Fasting is commonly used to study skeletal muscle. Enrichment is social housing and we will ask RRC to provide nestlets. Mizushima et al, 2004 found that fast twitch muscle such as in the gastrocnemius and in organs such as the liver and pancreas 24h starvation is sufficient to induce autophagy. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC363084/ and Paul et. al 2012 produced similar results https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3302447/	skeletal muscle wasting	up to 24 hours	None--terminal procedure	Water is provided ad libitum.
18398	Haberzettl, Petra	Mouse	Food restriction to 12 h per day that have been shown to reset circadian rhythm and to be beneficial for metabolic health will be used to test whether restricted access to food protects against the effects of CAP exposure, circadian dyssynchrony and their combination.	food restriction to 12 hours per day	up to 30 days	Animal health will be monitored, e.g. body weight will be measured regularly.	Water is provided ad libitum. [redacted]
18231	King, Suzanne N	Rat	To assess swallowing, lick, and chewing function requires the animals to eat and drink. Inducing thirst/hunger prior to palatability testing, behavior conditioning, lick testing, chewing performance assay, and VFSS by regulating food or liquid water has been shown to increase the likelihood of participating during these tasks. This helps to limit the amount of radiation exposure to the animal during VFSS and reduce the length of testing time. During behavior conditioning we will test the motivation of the animal to perform the eating tasks after different periods of fluid or food restrictions (2-6hrs; max of 18hrs). We will use highly palatable materials to try to limit the restriction to as low as possible. The goal is for the animal to be thirsty or hungry. The least amount of time required for adequate participation will be used.	Withholding liquids or food;	2-6 hrs; or overnight; Max of 18hrs [redacted]	The goal of water and food regulation is for animals to be thirsty/hungry, not dehydrated or starved. Animals activity will be monitored for evidence of lethargy and/or changes in general appearance or social behaviors.	Restrictions will progress stepwise and no longer than necessary restriction will be used. Fluids and food will be given if there are signs of dehydration, such as lethargy and/or skin does not spring back when stretched. [redacted]
18231	King, Suzanne N	Rat	To improve the accuracy of swallowing assessment with VFSS, the volume and rate of bolus administration may be controlled. This will allow us to test various bolus types and/or consistencies w/ or w/o contrast reagent during a fluoroscopic session.	controlling volume and rate of bolus administered	2-4 hrs; overnight(max 12-14hrs)	General appearance (e.g. grooming (under or over), eyes, breathing rates, social behaviors) will be monitored for assessment of general well-being.	Rats will be given fluids in the event of signs of dehydration.
19660	McGee, Aaron W	Mouse	Motivation for performance of head-fixed behavioural assays - In pilot experiments, mice lost weight and some mice performed as desired. However, the variability was greater than expected. A recent study reported that maintaining rats and mice on 1% citric acid water available ad libitum in the home cage is sufficient to motivate rodents for task performance rewarded with small amounts of water containing sucrose (10%). - these procedures have been revised to adopt this new strategy that offers mice water more consistently throughout the day.	- water containing 1% citric acid available ad libitum in home cage with supplementation of water containing 10% sucrose to 1 ml total per day to achieve a 15% - 20% reduction in body weight	3-4 weeks	daily	We will employ a published standard for the semiquantitative physical assessment for activity, posture and grooming, signs of eating and drinking, and signs of dehydration, as described for in the Janelia Farms Campus health assessment flow chart published by our collaborator in a recent methods paper 'Procedures for Behavioral Experiments in Head-Fixed Mice' Guo, et al. 2014, PLoS One. This manuscript, the health assessment flow chart and health assessment score sheet are all attached as supplemental material. The goal is to stabilize body weight at 15% to 20% of the original body weight over 7-10 days to motivate performance on a head-fixed visual task. - a published study in attached describing the benefits of water regulation by ad libitum availability of cage bottle water containing 1% citric acid Adult mice will undergo water regulation in preparation for behavioral conditioning by adding 1% citric acid to their available water. Published studies in rats (published) reveal this is mildly aversive resulting in the desired range of body weight loss , and is sufficient to motive rodents to perform for water containing sucrose. Mice are weighed and examined daily. Their weight and appearance are charted daily to evaluate their relative loss of body weight and overall health. Mouse are single housed or in small groups of siblings. Dry food is continuously available. - water containing 1% citric acid is constantly available. - Mice typically converge on a reduction of body weight by 20% within 7 days according to published reports. Mice are monitored daily for hydration, weight, movement and ruffled fur. If mice approach 70% of pre-restriction body weight, or show signs of dehydration, such as abnormal gait, lack of mobility, hunched posture, extensive ruffled fur, no feces, and or skin that tents and remains tented when pinched, they are provided supplemental water in the range of 0.5 – 1 ml immediately depending on the severity of symptoms. Water supplementation will be continued per day until these symptoms are resolved. During this time mice are monitored twice daily until they increase in body weight and health assessment.
18265	Zhang, Huang-Ge	Mouse	For glucose tolerance and Insulin resistant tests, fasting is essential for measuring blood glucose.	no food given	4-12 hours [redacted]	make sure mice remain active.	measure body weight. [redacted]

IACUC	PI	Species	Description	Duration	Acclimation	Monitoring	Adverse Events	Removal Criteria
18248	Gomes, Cynthia	Rat	The device is a "Quonset hut" design. It is essentially a length of plexiglass tubing cut in half along its long axis. It has cut-outs to allow for 1) insertion of barriers to ensure proper fit of the functional length of the device to the size of the rat and 2) stimulators (e.g., forceps, heat probes) to access the back skin that is the site of stimulation and recording. The device would be inverted over the rat and secured to the surface. The justification is that the CTMR, although robust and resistant to some anesthetics, is not immune to anesthetics. The best results may come from assessing the CTMR in non-anesthetized animals. The CTMR itself is a reflex system worthy of study because of its planar and somatotopic anatomy, and the fact that both the amplitude and duration of the CTMR can be measured fairly easily/accurately, while most nociceptive reflex systems measure only the latency-from-stimulus, but not amplitude and duration. It must be well-noted that the procedure, including the device, are in development. It is entirely possible that we will have to re-design the device based on the results of real life use.	Because we have not yet established any true sense of the variability in this procedure, the information provided in this section is an "educated guess". Any adjustments to the procedures outlined here will be done in accord with RRC staff, and with a modification to the protocol as is appropriate. We expect the animals to spend no more than 20 minutes in the restraint device for testing sessions.	All animals will be provided 5-15 minutes of access to the devices in their home cage for 3-5 days. Then animals will be given access to the device outside of their cage, both in a neutral cage and for brief periods on a benchtop or tabletop where the measurements would actually be performed, for 5-15 minutes per day for 3-5 days. Animals will then be placed into the device with no testing done, for increasing durations up to 20 minutes. They will be monitored constantly and provided treats such as cereal and small pieces of apple. We will then begin "testing-training", which will consist of 2-5 sessions (1/day; increasing duration up to 5 minutes) with delivery of the same kind of stimuli as would be used for data acquisition, but the session would be briefer than an actual session and if data are acquired, they would not be included in the analysis. Data may be used to help determine consistency of responses and efficacy of the acclimatization procedures. [N.B. The device will be washed with soapy water after each use to minimize the carryover of scent and any other biological material that may induce undue stress.]We do now know a priori if these procedures will be sufficient. Part of the experimental process will include documentation of the acclimatization procedures to enable us to troubleshoot and alter the procedures if necessary. We may also need to alter the device if we observe that some aspect of the restraint stresses the animals to greatly. We will work with RRC staff and the KSCIRC staff (who have extensive experience with rodent behavioral measures) to make adjustments to the procedures if necessary.	times when in the device. Aside from the data collection procedure, which itself is video recording, animals will be observed for signs of stress or discomfort that may require attention and possible action. Animals will be observed for movements which result in them getting caught incorrectly in the device such that they could be injured, for attempts to escape that may result in injury, freezing behavior indicative of fear and stress, seepage of fluids from eyes or nose indicative of severe stress.	We will closely monitor the animals while in the device and in case of adverse situations, we will release the animal. In occurrence of any bodily injury, like scratching or small cut, we will use antibiotic ointment to cover the wond and consult to veterinarian if needed.	The types of observations would include direct self-harm, potential for immediate self-harm, persistent full-body movement/squirming that would interfere with assessments, movement into an actually or potentially harmful or stressful body-position. In addition, severe responsiveness to stimuli (vocalization, panting, grimacing, etc.) would warrant either early release or a limitation of the range of stimuli to those that yielded observable responses without the extreme responses (i.e., limit the stimuli to the low-range). The device is a "first generation" device and we may discover that additional sizes or physical features are required for optimal functioning with minimal opportunity for harmful situations. The investigators will work with RRC and other experienced animal behavior observers to develop modifications if necessary.
18337	Guido, William	Mouse	Head-fixed training used to keep the head still while electrophysiological recordings are done in the brain	No more than 1 hour	Mice will be acclimated 2 days following head-plate implantation for a period ranging from 10 minutes to 1 hour for one week prior to electrophysiological recordings.	Animals will be continuously observed while in the head-fixed apparatus.	Animals will be euthanized if they meet the endpoint criteria as listed in section 29.5	Animals will be immediately removed from the apparatus if they exhibit any signs of stress. [redacted]
19437	Samuelsen, Chad L	Rat	The restraint device is a plexiglass box with a small hole in the front where a bolt, previously affixed to the rats head during surgery, is secured during the experiment. The restraint procedure is used in many laboratories on many species of animal subjects. The restraint preparation offers many experimental advantages for behavioral electrophysiology. It allows for an unambiguous and unobstructed view of the face of the animal, which is fundamental for analyzing the consummatory behaviors produces by rodents. Visualizing and quantifying these behaviors is a standardized experimental procedure to measure the palatability of tastes, which is made more difficult and less rigorous by animal head movements. Experimental procedures in awake animals, specifically electrophysiological, pharmacological, and intraoral presentation of tastes and odors, require the electrodes and the cannulae (secured on the head of the animal) to be connected to equipment located several feet away. The presence of multiple long wires and tubing connected to the head of the animal, presents a major challenge for the stability of the implants. An animal's activity can often result in twisted wires and tubing, experimental artifacts and unnecessary animal distress. Another fundamental advantage of the restraint preparation is that it avoids all the movement related problems to the experimental harness. This allows for "cleaner" recordings and imaging of neural activity, intracranial infusions of drugs and reliable deliveries of chemosensory stimuli.	Restraint occurs only once per day. The duration of the restraint training and experimental session will vary between 10 minutes up to 90 mins (at most). Most experimental sessions are completed in 45-60 min. The frequency of the sessions will be daily for a period of a 4-6 weeks.	After 7 days of surgical recovery and 5 days of handling and water regulation, animals will be introduced to the restraint box. During the first 3 days, animals will be familiarized with the restraint box. After 5-10 min of adaption, animals will be returned to their home cage and receive 60 min of water. During the first restraint session, ~40 uL of water will be delivered directly into the mouth via IOC every 7-10 sec. The delivery of water is rewarding and will motivate the animal to sit calmly. The water delivery time will be gradually increased over subsequent training sessions. Once the animal has learned to wait calmly for 10sec inter-delivery-interval, the animal will start training on specific tasks. This training procedure has been commonly used to train animals to calmly wait for fluid delivery for period of up to 90 mins.	Animal's behavior, vocalizations, task performance, fluid intake and physical reaction will be constantly monitored via video camera during the entire training and/or experimental sessions	If there are adverse clinical events, we will stop training and seek evaluation by veterinary staff.	In the extremely rare occurrence an animal fails to habituate to restraint or fails to drink fluid delivered via IOC for a period of 7 days, it will be removed from both the task and water deprivation.
18232	Boakye, Maxwell	Pig	A mobile restraint unit or Panepinto Sling which are made from a heavy cotton or canvas material and they have four leg openings. The unit may be used to restrain animals for urodynamic assessments.	will not exceed 30min of restraint	All animals will be acclimated to the sling prior to usage using positive reinforcement training and will be monitored the whole time while being restrained.	Animal will be observed while in the sling	Veterinary care will be present during procedure.	Animals that do no adapt to the restraint device will be removed from this portion of the study.

Restraint

IACUC	PI	Species	Description	Duration	Acclimation	Monitoring	Adverse Events	Removal Criteria
20773	Hubscher, Charles H	Rat	Treadmill training involves the use of a harness that supports the rat's body.	58 minutes per day, 5 days a week for up to 8 weeks	A pre-training period of at least two half hour sessions is first done to acclimate each rat to the treadmill system/procedure. This is done unrestrained. After spinal cord injury but prior to training, all rats are placed in the harness on the treadmill for a period of 20 minutes for two sessions. Once training begins, the step trained animals will be placed on the treadmill in the harness for 20 minutes beginning at a slow speed and gradually increasing the speed. The session time is increased from 20 minutes to the target amount of 58 minutes over the course of the first 10 days after the beginning of training. An animal that does not acclimate to the harness after two full sessions is removed from the study.	All rats on the treadmill are monitored by an experienced investigator at all times.	Stop training and seek evaluation by the veterinary staff	Used for the control group (never has occurred)
20695	Tyagi, Suresh C	Mouse	Mice will be suspended by the tail for a period of one week to induce skeletal muscle atrophy via hindlimb unloading. This is accomplished using specialized cages. The cage is a plastic bin with a slotted-steel plate attached across the top of the bin and anchored via screws. A machined screw is inserted into a slot on the steel plate and held onto the steel plate by wing nuts and washers. The bottom tip of the screw, hanging inside of the plastic bin now, has a sewing machine bobbin held on to the screw by a locking nut. A paper clip is inserted into the machine bobbin, and formed into a hook hanging from the bobbin. Mice will be fashioned with a tail harness which consists of a cut pipette tip inserted over the tail that is wrapped with gauze and taped securely. A piece of nylon thread is tied to the pipette tip and into a loop. This loop can be hung on the previously mentioned paper clip "hook". The mice will be suspended at a 30-40 degree torso angle for a period of 1 week to allow time for significant atrophy to occur, according to previous research. Food will be secured inside of the cage as well as a water bottle attached and within reach at all times. The mice will have their hindlimbs suspended in the air, but will be able to walk around the cage on their forelimbs to access food and water, ad libitum. Bedding will be placed in the bottom of the plastic bin and changed routinely, as per typical. The cage will be covered with a clear plastic "rat-cage lid" that allows the mice to be protected from outside debris while also allowing the researchers to see into the cage. Rat-cage lids also have a microfiber barrier that allows air to enter the cage, while still protecting the mice from outside debris. Between uses of these cages, each cage will be cleaned and sanitized thoroughly before new mice are suspended.	1 week	The mouse will be hanged for 15 minutes everyday for one week for acclimatization. This is according to the paper: ."Protective effect of branched chain amino acids on hindlimb suspension-induced muscle atrophy in growing rats" Jiwoong Jang1 , Hea-Yeon Yun2 , Jonghoon Park1,2 and Kiwon Lim1,2* 1 Laboratory of Exercise Nutrition, Department of Physical Education, Konkuk University, Seoul, Republic of Korea 2 Physical Activity and Performance Institute (PAPI), Konkuk University, Seoul, Republic of Korea;	The animals will be determined to be in good health by analysis of appearance and normal (or typical) weight gain. We will check mice everyday for signs of distress and pain. Food and water will be replaced everyday. Bedding will be placed in the bottom of the plastic bin and changed routinely everyday.If the changes such as pain, illness, or distress include decreased appetite, weight loss, decreased spontaneous activity, abnormal gait or posture will be detected the veterinarian will be notified so that the animal can be evaluated.	N/A	Animals will be checked daily for signs of pain or distress. following will be considered as signs of distress or pain: abnormalities include not normal weight gain, lethargy, depression, reluctance to move, weakness, or hunched posture,ruffled fur or unkempt appearance, signs of dehydration, and hypothermia. Specific attention will be given to the ability of the animal to acquire food and water. The animals with the above mentioned signs will be removed from the study.
19660	McGee, Aaron W	Mouse	Head-fixed restraint by means of a custom aluminum head plate affixed to the skull with dental acrylic. Mice are positioned upon a styrofoam ball permitting ambulations while remaining head-fixed	one hour or less	Daily acclimation for three days for 15 minutes or longer prior to initiating training	Mice are monitored for loosening of the head plate from the acrylic base and the acrylic base adhering to the skull - Mice are inspected daily - In addition, a researcher monitors the animal through a video camera placed inside the behavior box during task performance. A researcher is in the same room at the mouse throughout the acclimation, training, and testing sessions	Mice suffering from adverse clinical events will be euthanized by carbon dioxide asphyxiation followed by cervical dislocation	Mice that manage to torque the headplate loose from the acrylic or dislodge the acrylic base will be euthanized by carbon dioxide asphyxiation followed by cervical dislocation
19606	Jala, Venkatakrishna R	Mouse	We will be examining stress-induced impact on gut barrier function, colitis. The following is well established in mouse models. Briefly, mice will be restrained in well-ventilated conical-bottom centrifuge tubes (50 mL; Corning) for 3 h daily during the procedure, not allowing forward and backward movement. (Ref: https://www.pnas.org/content/115/13/E2960; https://pubmed.ncbi.nlm.nih.gov/16862152/)	3 hours	The goal of this procedure is to generate the stress to these animals. We will not be acclimatizing the mice for this procedure. After exposure to stress mice will return to the normal cages.	Mice will be monitored during the procedure continuously on the day 1 to observe any abnormality during the procedure. After that we will have personnel to check every 45 min interval. Specific personnel will be assigned during the procedure.	Yes. We will adopt to veterinary care if there are adverse clinical events. We will be in contact with RRF staff during the procedure to gain more knowledge.	Animals will be weighed twice per week during the chronic restraint stress and removed from study if they lose > 15-20% body weight from baseline (body condition score < 2/5). Animals will also be monitored for lesions or injury associated with the restraint device and veterinary recommendations will be followed if any occur.

Restraint

IACUC	PI	Species	Description	Duration	Acclimation	Monitoring	Adverse Events	Removal Criteria
20746	Hubscher, Charles H	Rat	Treadmill training involves the use of a harness that supports the rat's body.	58 minutes per day, 7 days a week for up to 10 weeks	A pre-training period of at least two half hour sessions is first done to acclimate each rat to the treadmill system/procedure. This is done unrestrained. After spinal cord injury but prior to training, all rats are placed in the harness on the treadmill for a period of 20 minutes for two sessions. Once training begins, the step trained animals will be placed on the treadmill in the harness for 20 minutes beginning at a slow speed and gradually increasing the speed. The session time is increased from 20 minutes to the target amount of 58 minutes over the course of the first 10 days after the beginning of training. An animal that does not acclimate to the harness after two full sessions is removed from the study.	All rats on the treadmill are monitored by an experienced investigator at all times.	Stop training and seek evaluation by the veterinary staff	Used for the control group (never has occurred)
Multiple	Cardiology: Baba, Carll, Conklin, Haberzettl, Hill, Srivastava	Mouse	Kent Scientific CODA 6 dual tail cuff blood pressure machine.	up to 30 minutes per session	Briefly the animals will be trained prior to any exposure for the blood pressure measurements. This will consist of placing the animals in mouse holders on a heating pad and attaching the cuffs without taking measurements for at least 3 consecutive days up to 30 minutes of acclimation prior to actual measurements being taken.	Body temperatures are monitored by use of a handheld infrared thermometer	While we do not expect any adverse event, if such occurs we will contact RRC staff for guidance.	If an animals blood pressure does not stabilize within 10 minutes they will be returned to their home cage [and another attempt may be made at a later date]. [redacted]
20711	Boakye, Maxwell	Pig	A mobile restraint unit or Panepinto Sling which are made from a heavy cotton or canvas material and they have four leg openings. The unit may be used to restrain animals for urodynamic assessments.	Will not exceed 30 min of restraint	All animals will be acclimated to the sling prior to usage using positive reinforcement training and will be monitored the whole time while being restrained	Animal will be observed while in the sling	Veterinary care will be present during procedure.	Animals that do not adapt to the restraint device will be removed from this portion of the study.
20755	Mitchell, Thomas C	Rabbit	Commercially available rabbit snuggle	Anticipated less than 30 minutes but may run slightly longer if unforeseen difficulties occur. No animal will remain in the snuggle more than 1 hour	None is required. These soft snuggles are designed to calm rabbits and allow non-invasive procedures such as blood collection to be done without the use of anesthesia.	Vet staff will be monitoring the animals the entire time they are in the snuggle.	A vet will be called to examine the animal immediately if there is an adverse event.	If the animal stresses or is distressed in the snuggle it will be removed immediately [redacted]
19665	McCall, Maureen A	Pig	sling made for pigs/piglets	up to 2 hours	The piglets will be trained to lay in the sling by placing them in the sling for a short period on day 1 and increasing the time in the sling on subsequent days.	The piglet is monitored continuously while in the sling	Veterinary staff will consult with large animal veterinarians will immediately if any adverse clinical or behavioral events are noted.	If veterinary evaluations determine that pigs/piglets need to be removed from the sling or if a pig fails to acclimatize to the sling, anesthesia will be used instead.
19665	McCall, Maureen A	Pig	Apparatus for drug administration mixed in a food reward. The overall dimension is 93" long, 22" wide and 42" high. The dimension allow an entry door lines to line up with one door of the home cage and exit with the door of the next cage. The materials include stainless steel frame and bottom, removable aluminium sides and plexiglass or polycarbonate front piece. The pig will move from their home cage and into a chute that ends in a V-shape. When administration is complete, the pig then leaves the apparatus by a separate door and back into the home cage. To enhance motivation, we may perform the administration/training prior to feeding the animal.	up to 1 hour	Prior to use with the drug/food mixture, the pigs will be trained to approach the feeding tube for a reward. Then they will be allowed to enter the chute aligned with their home cage door, or they will be coaxed into the chute using verbal encouragement or food reward. Eventually they will learn to associate entry with the food reward delivered at the front of the chute.	The pig is monitored continuously entering, while in the chute and exiting the apparatus	Veterinary staff will consult with large animal veterinarians will immediately if any adverse clinical or behavioral events are noted.	If veterinary evaluations determine that pigs/piglets need to be removed from the chute or if a pig fails to acclimatize to the chute the vet staff will administer the drug in the home cage instead

IACUC#	PI	Species	Exception	EXCEPTION_DESCRIPTION	DURATION
20706	Severson, William E	Ferret	Space Exception (decreased cage size or housing density; see Note above)	[redacted] has traditionally housed ferrets in Allentown Ferret/ Rabbit racks (24 inches x 30 inches x 16 inches). These racks have double doors and are connected to HEPA filtered exhaust blowers to maintain primary containment at the cage level. A disadvantage to this caging system that the animals must be placed in a secondary transport container to be moved from the cage to the biosafety cabinet for any manipulation onc infected. This increases the risk that the animal can escape the cage and thus primary containment. Also shredded paper, food, and water tends to fall on the floor when the double door system is opened. Either of these events can represent a break in primary containment and in certain instances is reportable to the CDC. The depth of the cages also causes the handler to need to reach inside the cage and risk exposure. To circumvent these risks, the RBL would like to try housing animals in ABSL3 active infectious disease studies in the Allentown Nex Gen Rat 1800 ventilated caging system (23 inches x 26 inches x 11.2 inches). The advantage of this caging system is that the cage itself can be removed from the rack and transferred to the biosafety cabinet preventing the need to transfer the animals to a secondary container and the fact that the cage is only opened inside a biosafety cabinet thus preventing "spills" of contaminated paper, food, and water onto the floor. Also, the need for handlers to reach into cages to capture animals would be eliminated. This caging system is used for ABSL4 studies in ferrets at the Rocky Mountain Laboratories NIAID/NIH Facility. The official ACLAM endorsed book for ferrets "Biology and Diseases of the Ferret 3rd edition" by James Fox and Robert Marini references the use of "a solid plastic cage measuring 14.5 inches x 9.4 inches x 9.8 inches" sourced from the UFAW Handbook on the Care and Management of Laboratory Animals. Despite the fact that these cages are used for this purpose at other facilities and similar sized caging is referenced, this should be considered a "non-standard size cage" and there are concerns about the limited floor space and height of these cages. In response to these concerns, Rocky Mountain RBL reported that "Since the ferret's normal posture is usually walking on all fours, we have not had an issue with concerns about the height of the cages. The animals are still able to get up on their hind legs, and they do so. We also add tubes/huts as environmental enrichment and have found that they spend most of their time playing in and around them." We are requesting approval to try this caging along with PVC pipes as enrichment on the cage floor to see how the animals adjust to the floor space and height. We may also need to determine whether it is best to acclimate the animals in this type of caging or only use it for active infectious studies. Animal will be monitored by RRF veterinary staff daily. Should any adverse/detrimental effects be noted, animals will be moved to the traditional housing immediately, even if mid-study. Only studies involving single housing will utilize this caging system.	Ten days for the pilot study (Group 2) to evaluate how well the animals adjust to the NexGen 1800 cages.
20706	Severson, William E	Ferret	Space Exception (decreased cage size or housing density; see Note above)	approval was granted for use of the Allentown NexGen 1800 IVC system for housing ferrets for up to 14 days. For Experimental Group 4, two days prior to virus challenge, animals will be transferred to NexGen 1800 cages and moved into the ABSL3 for acclimation. Following challenge, animals will be housed another 12 days prior to study end, for a total of 14 days.	14 days
20757	Magnuson, David S	Rat	Space Exception (decreased cage size or housing density; see Note above)	Only applicable to the studies that are testing activity restrictions. During the hours of 6PM to 6AM the animals are placed in Special housing conditions that are pre-approved, and dependent on the conditions of the study. Two examples are a small cage to restrict movement measuring 21.5cm x 19cm, and a Large cage to encourage extra movement measuring 55cm x 37cm. The animals will be marked in order to identify the animal by either shaving, or by marking with a sharpie pen. The cages are placed on special racks that contain video cameras to record, and infrared lights to provide illumination for the cameras without creating illumination for the animals. The cameras will record in a time-lapse function during those hours as the animals go about their normal activity. Videos are later assessed to determine the total distanced that they walked in the cages, as well as noting any exhibited in cage behaviors.	Up to 8 weeks unless otherwise stated in individual protocols.

IACUC#	Investigator	Species	Exception	EXCEPTION_DESCRIPTION	DURATION
20754	Barve, Shirish S	Mouse	Housing Temperature Range	The alcohol diet induce hypothermia in mice which leads to higher mortality. Hence, the alcohol-feeding studies will be conducted in a warmer climate rooms, set at 75 °F. Some studies will be conducted at 86°F (range 80-89°F) to mimic the thermoneutral zone (TN), or temperature of metabolic homeostasis of mice. The TN zone for mice have been shown to lower stress-driven corticosterone, augmented mouse pro-inflammatory response and markedly exacerbated liver pathogenesis due to high-fat diet (doi:10.1038/nm.4346). The biological response of mouse at TN zone also reflects the activation of inflammatory pathways that are associated with disease in humans.	Duration of the experiment. The experimental duration may be up to 8 weeks.

USDA Exceptions

IACUC#	PI	SPECIES	EXCEPTION	EXCEPTION_DESCRIPTION
18290, 18232	Boakye, Maxwell	Pig	Space Requirements	Animals are retained in a small, padded vari-kennel crate immediately following surgery (approximately 7 days) to prevent self-injury, removal of catheters, and to facilitate special nursing care.
19664, 19665	Dean, Doug; McCall, Maureen	Pig	Space Requirements	Just prior to farrowing sows are housed in a pen modified to prevent crushing of pigs yet maintaining their ability to nurse. Floor space in the farrowing pen is limited and does not allow the sow to turn around. Once farrowing is complete and the pigs are nursing well, the floor space for the sow is progressively increased to the standard size.
17164, 19510, 19543	Howland, Dena; Pitts, Teresa	Cat	Lack of resting boards	After surgery, animals will be housed with bedding. Resting board wil be removed to avoid pressure sores or peripheral nerve damage with compromised sensation in rear limbs.
19543, 19510	Howland, Dena	Cat	Lack of litter box	During transit to a collaborating institution, an absorbent pad is used rather than a litter box to avoid peripheral nerve and/or skin compression.
20779	Giridharan, Guru	Sheep	Space, Tethering	Animals will be housed individually post device implantation for the duration of the study in reduced sized pens that restrict their ability to be able to turn around to prevent extrication or chewing on percutaneous externalized cables and central lines. Tethering allows the animals to eat, drink, stand, lie down, and tend to all physiological needs. They may also have a jacket and/or line patches placed to support any externalized lines. Animals will be acclimated for at least 48 hours prior to surgery. They will be monitored 24/7 after surgery b postoperative animal care attendants. Animals that do not tolerate restraint well will be removed from the study

Ventilation

IACUC#	PI	Species	Exception Type	EXCEPTION_DESCRIPTION	DURATION
19546	Cai, Lu	Mouse	Housing Ventilation Rate (low rate, use of recycled air)	animals are maintained in standard cages but in chronic hypoxia (10%) for 4 weeks in SHAD [redacted] and [redacted] Nonhypoxia controls are maintained in the same rooms/cages with room air. See the attached SHAD for additional details.	4 weeks.

University of Louisville

Satellite Housing Area Description

[redacted]

Reminders:

- Animals must be observed and monitored at least once daily.
- The justification for keeping rodents within a non-RRF space longer than 12 hours must be detailed in the "Special Housing" section of the *Proposal* (item IX.D. [old form], Section 7 [new form], or Section"Non-RRF Study Sites" in IRIS). *Keeping of animals in laboratories or satellite facilities for reasons other than those procedures approved by the IACUC is prohibited.*
- The RRF Veterinarians must retain independent access to the area.
- The names and contact numbers (including emergency contact numbers) for individuals responsible for animal observations in the area must be posted. *Note that RRF veterinary care staff must be notified immediately of veterinary medical issues (abnormalities including illness, abnormal behavior, or mortality).*
- Light cycles should be controlled and correspond to the same on-and-off cycle as the vivarium of origin.
- The date the cage entered the room and the date the cage was returned or the animals were euthanatized must be noted on a cage card. If all cage occupants are euthanatized, these cage cards must be retained for at least 3 years and made available to the IACUC and RRF for review.
- An addendum to the SHAD must list all pertinent IACUC-approved *Proposals.*
- This SHAD should be updated and revised as often as necessary but at least every three years.

Facility(ies) Description

1. Personnel Responsible for Animal Care.

Name	Work Contact Number	Emergency Contact Number
Jun Cai	502-852-3771	[redacted]
Tianci Chu	502-852-2217	[redacted]
Karen Powell	[redacted]	[redacted]
Amanda Ryan	502 -852-3730	[redacted]

(To add rows, place cursor in bottom-right cell and press TAB.)

2. Room Identification.

Building	Room No.	Estimated Area Used (ft^2) for Housing	Estimated Area (ft^2) Used for Support
[redacted]			

(To add rows, place cursor in bottom-right cell and press TAB.)

3. Room Description. In the space below, describe the finishes/materials used in the room(s) listed above, including floors, walls, doors, and ceilings. Surfaces should be maintained to enhance sanitation practices.

Doors are wooden. Floors are coated with 12x12 vinyl tile. Walls and ceilings are 5/8" drywall painted with epoxy paint.

4. Emergency Power.

a. What systems in the rooms listed above are equipped with emergency power?

[redacted] (applies to both of these rooms) air handlers are on emergency power (back up generator) for heating/cooling*.

b. If HVAC systems are not equipped with emergency power, then describe your plans for responding to power outages and other support system failures.

[redacted]

5. Lighting system(s). Describe lighting system(s) for the animal housing rooms, including estimated light intensity, spectrum, photoperiod (light:dark), construction features (*e.g.,* water resistance), and control (*e.g.,* automatic versus manual, phasing). For systems automatically controlling photoperiod, override mechanisms should be described. Exterior and interior windows should be opaque or red-filtered.

[redacted]

6. Safety Features. Describe safety features of the areas, including electrical hazard safety and physical hazards.

Electrical receptacles in the rooms are GFI.

7. **Security.** Describe security measures used in the area.

[redacted]

8. **Pest Control.** Describe pest control programs supporting and/or affecting the housing room(s).

Insect monitoring traps will be obtained from the RRF. Areas in and around the area will be carefully monitored (visually) for evidence of rodent vermin.

9. **Heating, Ventilation, and Air-Conditioning (HVAC) System.** *Note: if more than one room is included in this Description, then a completed "AAALAC HVAC System Summary Form" must be attached.*

   a. **Is supply air 100% fresh and is exhaust air 100% exhausted (i.e., not recirculated)?** [X] **Yes** [ ] **No**
   If "No," then in the space below please describe the source of air supply (including %) and describe how much (%) and to where exhaust air is returned. [**Link to AAALAC FAQ regarding use of recycled air]**

   b. **Describe any treatment of the supply air (filters, absorbers, etc.) in the space below.**

   [redacted] do not have additional filtering.

   c. **What is the room ventilation rate (in room air changes per hour)?** See below

   [redacted] air changes are 8.6/hr. at full heat and 24.8/hr. at full cool.*
   [redacted] air changes are 33.7/hr.*

Both rooms utilize static cages but room [redacted] is equipped with a one small animal microisolator rack (Forma Scientific) that can house 20 small or 12 large static microisolator cages after hypoxic

treatment. The rack creates a laminar flow of air which aids in biosecurity and decreases odor/allergens.

Note: If static microisolator cages are used, room air exchange rate should exceed 10 air changes per hour. If individually-ventilated cage systems are used, air exchange rate should be adequate to support temperature and relative humidity in Guide-recommended ranges and prevent odor escape into surrounding areas.

d. Is the room relatively negative with respect to the surrounding areas? [X] **Yes** [ ] **No**

If "No," please explain in the space below:

[redacted] has a supply air of 600 and an exhaust flow of -600 making it neutral to [redacted] has a supply of 672 (low flow heating) and 2247 (high flow cooling) with an exhaust of -852 (low flow heating) and -2450 (high flow cooling) making it negative to the adjacent hallway. *

e. Is relative humidity controlled in this room? [ ] **Yes** [X] **No**

f. Will the room (or cage) be maintained within Guide-recommended temperature (+/-2°F with a set-point between 70-72°F) and relative humidity (30-70%) ranges? [ ] **Yes** [X] **No**

If "No," please explain in the space below:

[redacted]

g. Is the room equipped with a means of monitoring temperature and notifying personnel in the event that critically high or low temperature (+/-7°F from set-point) is reached? [X] **Yes** [ ] **No**

If "No," please explain in the space below:

h. Will the HVAC equipment performance be evaluated at least annually? [X] **Yes** [ ] **No**

If "No," please explain in the space below:

i. Provide the date of the last assessment of the HVAC system (*e.g.*, used to calculated the air exchange rate for question "c" above).

Date of last assessment – 12/2015 as per David Darnell Annual HVAC assessments are performed by physical plant annually for all animal holding areas including these two rooms.

Primary Enclosures

1. Will standard RRF-provided caging be used? [X] **Yes** [ ] **No**

If "Yes," proceed to question 2. If "No," please complete the following table for ***each*** special primary enclosure (cage) used:

Name / Identifier[1]	Species Housed	Composition[2]	Length[3]	Width[3]	Area[3] (LxW)	Height[3]

(To add rows, place cursor in bottom-right cell and press TAB.)

[1]Create a name/identifier for reference.
[2]Provide a brief description of the materials used in construction (*e.g.*, Nalgene, polysulfone, glass).
[3]Provide units (inches or centimeters).

Notes:

a. [redacted] is equipped with three identical custom-designed chambers (15"x16"x16") and four standard chambers (30"x20"x20") to be operated by an OxyCycler A-Series controller (BioSpherix, Lacona, NY). These may hold up to 22 small static microisolator cages of mice (5 adult/cage or single female with pups) or 11 large static microisolator cages of rats (2 adult/cage or single female with pups) for hypoxia exposure. All chambers are constructed of clear plastic, white polypropylene, and stainless steel.
b. [redacted] is equipped one small animal microisolator rack (Forma Scientific) that can house 20 small or 12 large static microisolator cages after hypoxic treatment. The rack creates a laminar flow of air which aids in biosecurity and decreases odor/allergens. It was certified on 4/16/15.
c. A maximum of 100 adult mice or 24 adult rats will be maintained in these rooms at one time.

2. Will the maximum density meet Guide space recommendations? [X] **Yes** [ ] **No**
In other words, will each animal be provided the space recommended by the Guide when housed simultaneously in the enclosure/cage?

If "No," please explain in the space below, and describe the performance criteria used to determine the appropriateness of the space allowance:

3. Are all instances of individual housing described and justified in the IACUC-approved Proposal? [X] **Yes** [ ] **No**

If "No," then a modification to each *Proposal* must be submitted for IACUC review and approval. The Proposal should also include a description of any elements used within the primary enclosure to enhance animal well-being (*e.g.,* environmental enrichment) while individually-housed.

Husbandry Practices

1. Will all animal husbandry, including daily observations and cage-changing be provided by RRF staff in accordance with RRF Standard Operating Procedures? [X] **Yes** [ ] **No**

If "No," please describe who (laboratory vs. RRF personnel) will be responsible for conducting daily observations, cage-changing, and other husbandry practices in the space below.

All husbandry practices will be performed by RRF staff. Laboratory staff will move animals/cages between the holding area [redacted] and the hypoxia chambers [redacted]

2. Will laboratory staff be responsible for any husbandry practices? [ ] **Yes** [X] **No**

a. Please confirm the following:

[X] All animals will be checked daily, including weekends and holidays. This will be recorded.

[X] The laboratory has defined methods of contacting animal care and/or veterinary personnel in case of an emergency.

[X] All personnel responsible for observing the animals have been trained to recognize signs of pain, distress, infection, and other illnesses in the species housed, and have been instructed to contact veterinary staff for assistance upon recognizing any such signs.

b. Will clean cages be obtained from the RRF as complete "kits" and cages changed "in toto," thus precluding the need to store feed, water, and/or bedding? [X] **Yes** [ ] **No**

If "No," please explain in the space below. Include details such as storage of caging, feed, bedding, and water (including locations).

Please describe the source, treatment, and method of providing drinking water in the space below:

c. Please confirm the following:

[X] Daily log forms will record animal census (for mice by cage, for rats by animal) for each separate *Proposal* number.

[X] Daily log forms will record the maximum and minimum temperature and relative humidity reached in the previous 24 hours, taken adjacent to the area of animal cage holding.

[X] Daily log forms will verify checking of feed, water, and an assessment of animal health.

[X] Daily log forms will record any animal abnormalities noted, including illness, abnormal behavior, or mortality. *RRF veterinary care staff will be notified immediately of such issues.*

[X] All records will be retained for at least 3 years and will be made available to the IACUC and RRF for review.

Attachment:

AAALAC Program Description Template, HVAC System Summary. (alternatively, you can provide the information in the space above).

* Information provided by David Darnell, Foreman U of L Controls Department, 12/21/15

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: October 9, 2020

1. Animal Care and Use Program NEW	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 NEW	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 NEW	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 (*Guide*, p 30) [must]	✓				

• Explanations of purpose and duration of restraint are provided to study personnel (*Guide*, p 30)	✓					
• Multiple surgical procedures on a single animal are justified and outcomes evaluated (*Guide*, p 30)	✓					
• Major versus minor surgical procedures are evaluated on a case-by-case basis (*Guide*, p 30)	✓					
• Multiple survival procedure justifications in non-regulated species conform to regulated species standards (*Guide*, p 30)	✓					
• Animals on food/fluid restriction are monitored to ensure nutritional needs are met (*Guide*, p 31)	✓					
• Body weights for food/fluid restricted animals are recorded at least weekly (*Guide*, p 31)	✓					
• Daily written records are maintained for food/fluid restricted animals (*Guide*, p 31)	✓					
• Pharmaceutical grade chemicals are used , when available, for animal-related procedures (*Guide*, p 31)	✓					
• Non-pharmaceutical grade chemicals are described, justified, and approved by IACUC (*Guide*, p 31)	✓					
• Investigators conducting field studies know zoonotic diseases, safety issues, laws and regulations applicable in study area (*Guide*, p 32)	✓					
• Disposition plans are considered for species removed from the wild (*Guide*, p 32)	✓					
• Toe-clipping only used when no alternative, performed aseptically and with pain relief (*Guide*, p 75)	✓					
5. IACUC Membership and Functions	**A***	**M**	**S**	**C**	**NA**	
• IACUC is comprised of at least 5 members, appointed by CEO (PHS Policy, IV.A.3.)	✓					
• Members include a veterinarian, a scientist, a nonscientist, and a nonaffiliated non-lab animal user (*Guide*, p 24)[ii]	✓					
• IACUC authority and resources for oversight and evaluation of institution's program are provided (*Guide*, p 14)	✓					
• IACUC conducts semiannual evaluations of institutional animal care and use program (PHS Policy, IV.B.)	✓					
• Conducts semiannual inspections of institutional animal facilities (PHS Policy, IV.B.)	✓					
• IACUC organizationally reports to the Institutional Official (PHS Policy, IV.A.1.b.)	✓					
• Methods for reporting and investigating animal welfare concerns are in place (*Guide*, p 23) [must]	✓					
• Reviews and investigates concerns about animal care and use at institution[iii] (PHS Policy, IV.B.)	✓					
• Procedures are in place for review, approval, and suspension of animal activities[iv] (PHS Policy, IV.B.)	✓					
• Procedures are in place for review and approval of significant changes to approved activities (PHS Policy, IV.B.)	✓					
• Policies are in place for special procedures (e.g., genetically modified animals, restraint, multiple survival surgery, food and fluid regulation, field investigations, agricultural animals) (*Guide*, p 27-32)	✓					
• Requests for exemptions from major survival surgical procedure restrictions are made to USDA/APHIS[v] (*Guide*, p 30) [must]	✓					
6. IACUC Training NEW	**A***	**M**	**S**	**C**	**NA**	
• All IACUC members should receive:						
o Formal orientation to institution's program (*Guide*, p 17)	✓					
o Training on legislation, regulations, guidelines, and policies (*Guide*, p 17)	✓					
o Training on how to inspect facilities and labs where animal use or housing occurs (*Guide*, p 17)	✓					
o Training on how to review protocols as well as evaluate the program (*Guide*, p 17)	✓					
o Ongoing training/education (*Guide*, p 17)	✓					
7. IACUC Records and Reporting Requirements[vi]	**A***	**M**	**S**	**C**	**NA**	
• Semiannual report to the IO (PHS Policy, IV.B.)						
o Submitted to IO every 6 months	✓					
o Compiles program review and facility inspection(s) results (includes all program	✓					

and facility deficiencies)						
o Includes minority IACUC views	✓					
o Describes IACUC-approved departures from the *Guide* or PHS Policy and the reasons for each departure[vii]	✓					
o Distinguishes significant from minor deficiencies	✓					
o Includes a plan and schedule for correction for each deficiency identified[viii]	✓					
• Reports to OLAW (PHS Policy, IV.F.)						
o Annual report to OLAW documents program changes, dates of the semiannual program reviews and facility inspections and includes any minority views	✓					
o Promptly advises OLAW of serious/ongoing *Guide* deviations or PHS Policy noncompliance (NOT-OD-05-034)	✓					
o 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]						
o Annual report to USDA contains required information including all exceptions/exemptions	✓					
o Reporting mechanism to USDA is in place for IACUC-approved exceptions to the regulations and standards	✓					
o Reports are filed within 15 days for failures to adhere to timetable for correction of significant deficiencies	✓					
o Promptly reports suspensions of activities by the IACUC to USDA and any Federal funding agency	✓					
• Records (PHS Policy, IV.E.)						
o IACUC meeting minutes and semiannual reports to the IO are maintained for 3 years	✓					
o Records of IACUC reviews of animal activities include all required information[x]	✓					
o 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 (*Guide*, p 14) [must]	✓				
• Direct or delegated authority is given to the veterinarian to oversee all aspects of animal care and use (*Guide*, p 14) [must]	✓				
• Veterinarian provides consultation when pain and distress exceeds anticipated level in protocol (*Guide*, p 5) [must]	✓				
• Veterinarian provides consultation when interventional control is not possible (*Guide*, p 5) [must]	✓				
• If part time /consulting veterinarian, visits meet programmatic needs (*Guide*, p 14)					✓
• Regular communication occurs between veterinarian and IACUC (*Guide*, p 14)	✓				
• Veterinarian(s) have experience and training in species used (*Guide*, p 15) [must]	✓				
• Veterinarian(s) have experience in facility administration/management (*Guide*, 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]					
o Veterinary/other professional staff (*Guide*, p 15-16)	✓				
o IACUC members (*Guide*, p 17)	✓				
o Animal care personnel (*Guide*, p 16)	✓				
o Research investigators, instructors, technicians, trainees, and students (*Guide*, pp 16-17)	✓				
• Continuing education for program and research staff provided to ensure high quality care and reinforce training (*Guide*, pp 16-17)	✓				
• Training is available prior to starting animal activity (*Guide*, p 17)	✓				
• Training is documented (*Guide*, p 15)	✓				
• Training program content includes: (*Guide*, p 17)					
o Methods for reporting concerns (*Guide*, p 17)	✓				
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 (*Guide*, p 17)[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 (*Guide*, p 20)	✓				
o	Animal care and use legislation (*Guide*, p 17)	✓				
o	IACUC function (*Guide*, p 17)	✓				
o	Ethics of animal use and Three R's (*Guide*, p 17)	✓				

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 (*Guide*, p 17) [must]	✓				
•	Program covers *all* personnel who work in laboratory animal facilities (*Guide*, p 18)	✓				
•	Changing, washing, and showering facilities are available as appropriate (*Guide*, p 19)	✓				
•	Hazardous facilities are separated from other areas and identified as limited access (*Guide*, p 19)	✓				
•	Personnel training is provided based on risk (e.g., zoonoses, hazards, personal hygiene, special precautions, animal allergies) (*Guide*, p 20)	✓				
•	Personal hygiene procedures are in place (e.g., work clothing, eating/drinking/smoking policies) (*Guide*, p 20)	✓				
•	Procedures for use, storage, and disposal of hazardous biologic, chemical, and physical agents are in place (*Guide*, p 21)	✓				
•	Personal Protective Equipment for the work area is appropriate and available (*Guide*, p 21)	✓				
•	Program for medical evaluation and preventive medicine for personnel includes:					
o	Pre-employment evaluation including health history (*Guide*, p 22)	✓				
o	Immunizations as appropriate (e.g., rabies, tetanus) and tests as appropriate (*Guide*, p 22)	✓				
o	Zoonosis surveillance as appropriate (e.g., Q-fever, tularemia, Hantavirus, plague) (*Guide*, p 23)	✓				
o	Procedures for reporting and treating injuries, including accidents, bites, allergies, etc. (*Guide*, p 23)	✓				
o	Promotes early diagnosis of allergies including preexisting conditions (*Guide*, p 22)	✓				
o	Considers confidentiality and other legal factors as required by federal, state and local regulations (*Guide*, p 22) [must]	✓				
o	If serum samples are collected, the purpose is consistent with federal and state laws (*Guide*, p 22) [must]					✓
•	Waste anesthetic gases are scavenged (*Guide*, p 21)	✓				
•	Hearing protection is provided in high noise areas (*Guide*, p 22)	✓				
•	Respiratory protection is available when performing airborne particulate work (*Guide*, p 22)					✓
•	Special precautions for personnel who work with nonhuman primates, their tissues or body fluids include:					
o	Tuberculosis screening provided for all exposed personnel (*Guide*, p 23)					✓
o	Training and implementation of procedures for bites, scratches, or injuries associated with macaques (*Guide*, p 23)					✓
o	PPE is provided including gloves, arm protection, face masks, face shields, or goggles (*Guide*, p 21)					✓
o	Injuries associated with macaques are carefully evaluated and treatment implemented (*Guide*, p 23)					✓
•	Occupational safety and health of field studies is reviewed by OSH committee or office (*Guide*, p 32)	✓				

11.	**Personnel Security** NEW	**A***	**M**	**S**	**C**	**NA**
•	Preventive measures in place include pre-employment screening, and physical and IT security (*Guide*, p 23)	✓				

12. Investigating & Reporting Animal Welfare Concerns NEW	A*	M	S	C	NA
• Methods for investigating and reporting animal welfare concerns are established (*Guide*, p 23) [must]	✓				
• Reported concerns and corrective actions are documented (*Guide*, p 24)	✓				
• Mechanisms for reporting concerns are posted in facility and at applicable website with instructions (*Guide*, p 24)	✓				
o Includes multiple contacts (*Guide*, p 24)	✓				
o Includes anonymity, whistle blower policy, nondiscrimination and reprisal protection (*Guide*, p 24)	✓				

* **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:

Veterinary Care

Date: October 9, 2020

1. Clinical Care and Management NEW	A*	M	S	C	NA
• Veterinary program offers high quality of care and ethical standards (*Guide*, p 105) [must]	✓				
• Veterinarian provides guidance to all personnel to ensure appropriate husbandry, handling, treatment, anesthesia, analgesia, and euthanasia (*Guide*, p 106)	✓				
• Veterinarian provides oversight to surgery and perioperative care (*Guide*, p 106)	✓				
• Veterinary care program is appropriate for program requirements (*Guide*, pp 113-114)	✓				
• Veterinarian(s) is familiar with species and use of animals and has access to medical and experimental treatment records (*Guide*, p 114)	✓				
• Procedures to triage and prioritize incident reports are in place (*Guide*, p 114)	✓				
• Procedures are in place to address:					
o Problems with experiments to determine course of treatment in consultation with investigator(*Guide*, p 114)	✓				
o Recurrent or significant health problems with the IACUC and documentation of treatments and outcomes (*Guide*, p 114)	✓				
o Veterinary review and oversight of medical and animal use records (*Guide*, p 115)	✓				
• Procedures established for timely reporting of animal injury, illness, or disease (*Guide*, p 114) [must]	✓				
• Procedures established for veterinary assessment, treatment, or euthanasia (*Guide*, p 114) [must]	✓				
• Veterinarian is authorized to treat, relieve pain, and/or euthanize (*Guide*, p 114) [must]	✓				

2. Animal Procurement and Transportation / Preventive Medicine	A*	M	S	C	NA
• Procedures for lawful animal procurement are in place (*Guide*, p 106) [must]	✓				
• Sufficient facilities and expertise are confirmed prior to procurement (*Guide*, p 106)	✓				
• Procurement is linked to IACUC review and approval (*Guide*, p 106)	✓				
• Random source dogs and cats are inspected for identification (*Guide*, p 106)					✓
• Population status of wildlife species is considered prior to procurement (*Guide*, p 106)	✓				
• Appropriate records are maintained on animal acquisition (*Guide*, p 106)	✓				
• Animal vendors are evaluated to meet program needs and quality (*Guide*, p 106)	✓				
• Breeding colonies are based on need and managed to minimize numbers (*Guide*, p 107)	✓				
• Procedures for compliance with animal transportation regulations, including international requirements, are in place (*Guide*, p 107) [must]	✓				
• Transportation is planned to ensure safety, security and minimize risk (*Guide*, p 107)	✓				
• Movement of animals is planned to minimize transit time and deliveries are planned to ensure receiving personnel are available (*Guide*, pp 107- 108)	✓				
• Appropriate loading and unloading facilities are available (*Guide*, p 109)	✓				
• Environment at receiving site is appropriate (*Guide*, p 109)	✓				
• Policies in place on separation by species, source, and health status (*Guide*, pp 109, 111-112)	✓				
• Procedures in place for quarantine to include zoonoses prevention (*Guide*, p 110)	✓				
• Quarantined animals from different shipments are handled separately or physically separated (*Guide*, p 110)	✓				
• Procedures in place for stabilization/acclimation (*Guide*, pp 110-111)	✓				
• Policies in place for isolation of sick animals (*Guide*, p 112)	✓				
• Program is in place for surveillance, diagnosis, treatment and control of disease to include daily observation (*Guide*, p 112)	✓				
• Diagnostic resources are available for preventive health program (*Guide*, p 112)	✓				

3. Surgery	A*	M	S	C	NA
• Surgical outcomes are assessed and corrective changes instituted (*Guide*, p 115)	✓				
• Researchers have appropriate training to ensure good technique (*Guide*, p 115) [must]	✓				

• Pre-surgical plans are developed and include veterinary input (e.g., location, supplies, anesthetic and analgesic use, peri-operative care, recordkeeping) (*Guide*, p 116)	✓				
• Aseptic surgery is conducted in dedicated facilities or spaces, unless exception justified and IACUC approved (*Guide*, p 116)	✓				
• Surgical procedures including laparoscopic procedures are categorized as major or minor (*Guide*, pp 117-118)	✓				
• For nonsurvival surgery, the site is clipped, gloves are worn and instruments and area are clean (*Guide*, p 118)	✓				
• Aseptic technique is followed for survival surgical procedures (*Guide*, pp 118-119)	✓				
• Effective procedures for sterilizing instruments and monitoring expiration dates on sterile packs are in place (*Guide*, p 119)	✓				
• Procedures for monitoring surgical anesthesia and analgesia are in place (*Guide*, p 119)	✓				
• For aquatic species, skin surfaces are kept moist during surgical procedures (*Guide*, p 119)	✓				
• Post-operative monitoring and care are provided by trained personnel and documented (e.g., thermoregulation, physiologic function, analgesia, infection, removal of skin closures) (*Guide*, pp 119-120)	✓				

4. Pain, Distress, Anesthesia and Analgesia	**A***	**M**	**S**	**C**	**NA**
• Guidelines for assessment and categorization of pain, distress and animal wellbeing are provided during training (*Guide*, p 121)	✓				
• Selection of analgesics and anesthetics is based on professional veterinary judgment (*Guide*, p 121)	✓				
• Painful procedures are monitored to ensure appropriate analgesic management (*Guide*, p 122)	✓				
• Nonpharmacologic control of pain is considered as an element of postprocedural care (*Guide*, p 122)	✓				
• Procedures are in place to assure antinoception before surgery begins (*Guide*, p 122) [must]	✓				
• Guidelines for selection and use of analgesics and anesthetics are in place and regularly reviewed and updated (*Guide*, p 122)	✓				
• Special precautions for the use of paralytics are in place to ensure anesthesia[xiv] (*Guide*, p 123)	✓				

5. Euthanasia	**A***	**M**	**S**	**C**	**NA**
• Methods are consistent with AVMA Guidelines on Euthanasia unless approved by the IACUC (*Guide*, p 123)	✓				
• Standardized methods are developed and approved by the veterinarian and IACUC that avoid distress and consider animal age and species (*Guide*, pp 123-124)	✓				
• Training is provided on appropriate methods for each species and considers psychological stress to personnel (*Guide*, p 124)	✓				
• Procedures and training are in place to ensure death is confirmed (*Guide*, p 124) [must]	✓				

6. Drug Storage and Control NEW	**A***	**M**	**S**	**C**	**NA**
• Program complies with federal regulations for human and veterinary drugs(*Guide*, p 115) [must]	✓				
• Drug records and storage procedures are reviewed during facility inspections (*Guide*, p 115)	✓				
• Procedures are in place to ensure analgesics and anesthetics are used within expiration date (*Guide*, p 122) [must]	✓				
• Anesthetics and analgesics are acquired, stored, and their use and disposal are recorded legally and safely (*Guide*, p 122)	✓				

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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:

IV. Endnotes

[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].

[xiv] 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."

[xv] Part 3 Subpart A 3.8 - "...research facilities must develop, document, and follow an appropriate plan to provide dogs with the opportunity for exercise. In addition the plan must be approved by the attending veterinarian. The plan must provide written standard procedures..."

[xvi] Part 3 Subpart D 3.81 - "...research facilities must develop, document, and follow an appropriate plan for environment enhancement adequate to promote the psychological well-being of nonhuman primates."

[xvii] Part 3 Subpart A 3.6(c)(1) - "Each dog housed in a primary enclosure must be provided with a minimum amount of floor space, calculated as follows:
(length of dog in inches + 6)^2 /144 = required floor space in square feet)."

- Part 3 Subpart D 3.80 (b) - "Primary enclosures [for nonhuman primates] must meet the minimum space requirements provided in this subpart."

- In situations where the USDA regulations and the *Guide* differ with respect to space requirements, the larger of the two must be followed.