University of Louisville

Institutional Animal Care and Use Committee

Meeting Minutes

Thursday, 20 August 2020, 9:00 AM

Teleconference

Members Present:	**Members Absent:**	**Additional Attendees:**
Dr. Pascale Alard	Dr. Geoffrey Clark	Ms. Christie Black
Dr. Cynthia Corbitt	Dr. Sucheta Telang	Ms. Stacy Cantrell
Dr. Swati Joshi-Barve		Dr. Steven Davison, *Alternate for Dr. Karen Powell*
Dr. Amanda LeBlanc		Dr. Katie Emmer
Dr. Ben Lovely		Ms. Brigitte Foote
Dr. David Magnuson		Ms. Tegan Tulloch
Dr. Kenneth Palmer		
Dr. George Pantalos		
Dr. Karen Powell		
Dr. Mary Proctor		
Dr. Leslie Sherwood		
Dr. David Samuelson		
Ms. Kathleen Smith*		

*Not present for the entire meeting; see notes below

I. Call to Order and Approval of the Minutes from the Previous Monthly Meeting, 16 July 2020 (Attachment 1)

Dr. Pantalos called the meeting to order at 9:05 AM with 13 voting members present.

The minutes from the previous meeting were presented for review. *A motion to accept the minutes was **unanimously approved** (12 "in favor," none opposed, 1 abstention (Palmer)]*).

[Ms. Smith left the meeting following this discussion; voting member count = 12]

Christie Black, a visiting veterinary student from LMU, was introduced to the Committee.

II. Ratification of Approved *Proposals* (Attachment 2)

All Committee members had an opportunity to individually review "Proposals to Use Laboratory Animals in Research and Teaching" (*Proposals*) presented for IACUC approval. *The following proposals were ratified with all eligible votes in favor and abstentions due to a conflict of interest for the following:* 17027 (Pantalos), 17107 Kosiewicz (Alard), 18232 (Boakye [Sherwood]), 18290 (Boakye [Sherwood]), 18304 (Ng [Sherwood]), and 20771 (Kaufman [LeBlanc]).

New Proposals: 20771 20778 20783 20786 20792

Three Year Renewals: 20729 20735 20764 20765 20772 20773 20781

Modifications: 17027 17080 17107 17110 17152 17167 17174 18220 18232 18239 18295 18356 18402 18418 19469 19534 19543 19565 19566 19567 19568 19615 19625 19632 20695 20706 20743

Annual Review: 18290 18304

Tissue: 20797

Administrative Modification: 20725

III. Continuing Education, Policy Review, iRIS Improvements

A. IACUC Policy Modification, "Rodent Identification" (*Emmer)* (**Attachment 3**)
Dr. Emmer presented these revisions to the Committee which focused on revising the acceptable conditions for toe clipping to comply with the NIH's 2019 *Guidelines for Toe Clipping of Rodents*. Dr. Samuelson requested that the "rigorous scientific justification" in item 2(a) be changed to "compelling scientific justification." *A motion to accept the policy revisions with the additional change was **unanimously approved** (12 "in favor," none opposed, no abstentions]*).

B. IACUC Policy Modification, "Tissue Harvesting for Rodent Genotyping" (*Emmer*) (**Attach. 4**)
Dr. Emmer presented these revisions to the Committee which added a reference to the "Rodent Identification" policy for clarity. *A motion to accept the policy revision was **unanimously approved** (12 "in favor," none opposed, no abstentions]*).

C. IACUC Policy Modification, "Use of Postoperative Analgesia" (*Sherwood, Davison*) (**Attachment 5**)
Drs. Sherwood and Davison presented this policy to the Committee, which was revised to better outline expectations regarding the use of postoperative analgesia, including the use of multimodal analgesia and appropriate justification. *A motion to accept the policy revision was **unanimously approved** (12 "in favor," none opposed, no abstentions]*).

D. IACUC Policy Modification, "Performing Rodent Survival Surgery" (*Sherwood, Davison*) (**Attachment 6**)
Drs. Sherwood and Davison presented this policy to the Committee, which was updated to include references to the "Use of Postoperative Analgesia" for clarity and consistency. *A motion to accept the policy revision was **unanimously approved** (12 "in favor," none opposed, no abstentions]*).

E. IACUC Policy Modification, "Rodent Breeding Colonies" (*Sherwood, Tulloch*) (**Attachment 7**)
This policy was revised to require quarterly reporting of rodent breeding colony animal usage, as well as emphasize that animal usage must never exceed the IACUC approved total on the *Proposal*. *A motion to accept the policy revision was **unanimously approved** (12 "in favor," none opposed, no abstentions]*).

F. IACUC Policy Modification, "Proposal Expiration" (*Sherwood, Tulloch*) (**Attachment 8**)
Ms. Tulloch presented revisions to this policy, which clarified the proper procedures for describing continuing studies on an expiring *Proposal* that will be transferred to a "renewal" *Proposal*. *A motion to accept the policy revision was **unanimously approved** (12 "in favor," none opposed, no abstentions]*).

G. Proposed New IACUC Policy, "Field Studies" (*Powell*, *Sherwood, Tulloch*) (**Attach. 9 & 10**)
Dr. Powell presented this new IACUC policy which was recommended by the semiannual program review subcommittee during the Spring 2020 semiannual self-assessment. The new policy provides information on field investigation requirements, including those pertaining to observational field investigations. An information sheet is also included to assist investigators writing field investigation *Proposals*. [redacted] Dr. Corbitt requested that "field studies" under item 6 be corrected to "field investigations." Dr. Corbitt also offered to review the observational field investigations *Proposal* form and request feedback from members of her department that work with wildlife. *A motion to accept the policy revision was **unanimously approved** (12 "in favor," none opposed, no abstentions]*).

IV. Open Discussion / Full Committee Review

A. Open Discussion: Cardiology *Proposals* Update (*LeBlanc*)
Dr. LeBlanc has served as the Designated Reviewer on several complex and difficult cardiology *Proposals*, several of which have been brought to the IACUC for Full Committee Review or open discussion over the past few years due to concerns about multiple survival surgeries, the use of multimodal analgesia, and a cold-water stress test procedure. Dr. LeBlanc provided an update to the Committee on recent reviews related to those items. After discussions with the Principal Investigator and protocol manager, the cold-water stress test was removed, the number of surgeries was reduced, and appropriate scientific justification for the analgesia regimen was included within the *Proposals.*

V. Old Business

A. Follow Up Report: *Proposal* 20706, "Model development for emerging human coronaviruses in the ferret" (*Powell, Emmer*) – *No Report Expected*
There is no update at this time; the IACUC has not yet received a follow-up report from the investigator. None has been expected yet as they have not completed another study.

B. Humane Endpoints Proposal 19657 (*Pantalos*) (**Attachment 11**)
The Principal Investigator informed Dr. Pantalos that data has been archived and the laboratory is consulting with the vendor in respect to calibrating the system. The investigator expects to have a dataset to share with the Committee in a few weeks. Dr. Pantalos will reach out again prior to the next IACUC meeting.

C. PETA Open Records Request (*Sherwood*) (**Attachment 12**)
Dr. Sherwood shared a recent open records request from PETA which is vague and requests an unreasonable amount of records. Dr. Sherwood has provided large animal records in response to the request and is waiting to see if this response are acceptable.

VI. New Business

A. Adverse Event *Proposal* 19625 (*Pantalos*, *Sherwood*) (**Attachment 13**)
Dr. Pantalos summarized the adverse event report detailed in the attached letter for the Committee.

[Dr. Powell recused herself during the Committee's deliberation; Dr. Davison served as voting member; voting member count = 12]

The Committee discussed the report and the preventive action already taken by the laboratory and CMRU staff. The IACUC agreed that no further action is required. A letter will be sent to the investigator thanking him for the self-report. *A motion to accept the above course of action was* ***unanimously approved*** (*12 "in favor," none opposed, no abstentions]*).

[Dr. Powell returned following this discussion; Dr. Davison reverted to alternate, non-voting member; voting member count = 12]

B. Humane Endpoints *Pseudomonas Proposal* 19498 (*Sherwood, Tulloch*) (**Attachment 14**)
Dr. Powell requested that the IACUC Office determine if the IACUC had requested an update on the *Pseudomonas* studies in 2019. Attached for the Committee's review are the relevant meeting minutes and the letter sent to the investigators in April 2019. The Committee did not provide a deadline or timeline to the investigator, but did note that the approved endpoints were contingent

upon the IACUC's understanding that studies with a new experimental designed which would minimize pain and distress of animals enrolled in *Pseudomonas* studies more so than the previously designed studies. The Committee agreed that it would be appropriate to request an update from the investigator.

C. VA Spring 2020 Semiannual Program Review (*Sherwood*)
Dr. Sherwood informed the Committee that the VA's Spring 2020 semiannual program review, which is shared as part of the MOU between UofL and the VA, has been received. This item will be reviewed during the IACUC's Fall 2020 semiannual program review. Dr. Sherwood noted one of item of potential concern in the report, which was a potential conflict of interest as Dr. Proctor was listed as the only inspector of the facilities that she supervisors. Dr. Proctor noted that she was actually accompanied by another IACUC member, Paul, during the inspections. Dr. Proctor reached out to the VA administration about updating the report to reflect this, but they declined to update the report due to the administrative burden of having it approved.

D. Comparative Medicine Research Unit (*Sherwood*)
The Research Resources Facilities was recently renamed to the Comparative Medicine Research Unit to better reflect the purpose and mission of the animal care program. Dr. Sherwood noted that the IACUC policies that reference the RRF will need to be updated. The Committee agreed that this change could be made administratively by the IACUC Office. *A motion to allow the IACUC Office to administratively revise all IACUC policy references to the Research Resources Facilities was* ***unanimously approved*** (*12 "in favor," none opposed, no abstentions]*).

VII. Adjournment

The IACUC was reminded that the next meeting will occur via teleconference Thursday, 17 September 2020 at 9:00 a.m. *Meeting was adjourned at 10:24 AM.*

University of Louisville

Institutional Animal Care and Use Committee

Meeting Minutes

Thursday, 16 July 2020, 9:00 AM

Teleconference

Members Present:	**Members Absent:**	**Additional Attendees:**
Dr. Pascale Alard	Dr. Geoffrey Clark	Ms. Stacy Cantrell
Dr. Cynthia Corbitt	Dr. Kenneth Palmer	Dr. Steven Davison
Dr. Swati Joshi-Barve	Dr. David Samuelson	Dr. Katie Emmer
Dr. Amanda LeBlanc		Ms. Brigitte Foote
Dr. Ben Lovely		Ms. Tegan Tulloch
Dr. David Magnuson		
Dr. George Pantalos		
Dr. Karen Powell		
Dr. Mary Proctor		
Dr. Leslie Sherwood		
Ms. Kathleen Smith		
Dr. Sucheta Telang*		

*Not present for the entire meeting; see notes below

I. Call to Order and Approval of the Minutes from the Previous Monthly Meeting, 18 June 2020 (**Attachment 1**)

Dr. Pantalos called the meeting to order at 9:02 AM with 12 voting members present.

The minutes from the previous meeting were presented for review. *A motion to accept the minutes was* ***unanimously approved*** (*12 "in favor," none opposed, no abstentions]*).

II. Ratification of Approved *Proposals* (Attachment 2)

All Committee members had an opportunity to individually review "Proposals to Use Laboratory Animals in Research and Teaching" (*Proposals*) presented for IACUC approval. *The following proposals were ratified with all eligible votes in favor and abstentions due to a conflict of interest for the following:* 18306 (Ng [Sherwood]), 19549 (Martin [Powell]), 20726 (Moore [LeBlanc]), 20755 (Mitchell [Powell]), 20756 (Magnuson), 20757 (Magnuson), 20761 (LeBlanc), and 20779 (Giridharan [Powell]).

New Proposals: 19654 20712 20744 20752 20779

Three Year Renewals: 19545 20722 20723 20725 20756 20757 20774 20777

Modifications: 18205 18220 18240 18351 18399 19549 19647 19661 19665 20692 20706 20726 20727 20732 20755 20761

Annual Review: 17164 18306 19520

Tissue: None

Administrative Modification: 19599

III. Continuing Education, Policy Review, iRIS Improvements

A. IACUC Policy Modification, "Proposal Review and Approval" (*Tulloch)* (**Attachment 3**)

Ms. Tulloch presented these revisions to the Committee, which included formalizing response procedures if a Principal Investigator departs the University of Louisville and information about reviewer conflict of interest. *A motion to accept the policy revisions was* ***unanimously approved*** (*12 "in favor," none opposed, no abstentions]*).

B. IACUC Policy Modification, "Modification of an Approved Proposal" (*Tulloch*) (**Attach. 4**)
Ms. Tulloch presented these revisions to the Committee which focused on updates to the list of administrative *Proposal* modifications that are approvable by the IACUC Office. *A motion to accept the policy revision was **unanimously approved** (12 "in favor," none opposed, no abstentions]*).

C. IACUC Policy Modification, "Housing of Mice and Rats" (*Sherwood, Davison*) (**Attachment 5**)
Drs. Sherwood and Davison presented this policy to the Committee, which was revised to clarify that double litters from the same dam necessitate immediate intervention by RRF husbandry staff. *A motion to accept the policy revision was **unanimously approved** (12 "in favor," none opposed, no abstentions]*).

D. "If a researcher disagrees with a veterinarian's recommendations, whose say goes," *Lab Animal* January 2020. 49, 3-5. (*Sherwood*) **(Attachment 6)**
Dr. Sherwood presented this article which includes a scenario where a veterinarian recommends the use of multi-modal analgesia to minimize pain and distress based on current veterinary practices, but the Principal Investigator believes buprenorphine post-operatively is sufficient. The Principal Investigator does not provide any scientific justification for not following the veterinarian's recommendation to using multi-modal analgesia. The study was approved with buprenorphine only after a full Committee review.

OLAW and USDA-APHIS provided a response to the scenario and discussed the selection of appropriate analgesics and anesthetics and the role of the veterinarian as a subject matter expert. The IACUC's response in the scenario was in direct conflict with the PHS Policy and the Guide. PHS Policy explicitly requires the IACUC to determine that painful procedures will be performed with appropriate analgesia unless "justified for scientific reasons in writing by the investigator." The Guide states that "the selection of appropriate analgesics and anesthetics should reflect professional veterinary judgment as to which best meets clinical and humane requirements as well as the needs of the research protocol" (p. 121). Further, the Animal Welfare Act requires that the Attending Veterinarian has appropriate authority to ensure the provision of adequate veterinary care, which includes adequate pre- and post-procedural care in accordance with established veterinary medical and nursing practices (9 C.F.R. § 2.33(a)2, (b)(4)).

The IACUC discussed this article at length, including current review practices and the importance of ensuring all justification is provided in writing within the *Proposal*. The Committee agreed that the IACUC Policy "Use of Postoperative Analgesia" should be examined to determine whether revisions are needed to clearly establish expectations and requirements. The RRF veterinarians will examine the policy and return any recommended revisions for Committee review at the next IACUC meeting.

IV. Open Discussion / Full Committee Review

A. Open Discussion: Toe Clipping (*Emmer, Telang*)
Drs. Emmer and Telang brought this item to the Committee for discussion after a *Proposal* was submitted for review with questionable justification for toe clipping. Dr. Telang asked for clarification on what is considered appropriate justification and how to address the issue. Dr. Emmer also noted that the NIH revised guidelines on toe clipping in February 2019 and recommended revising the current policy to reflect best practice. Dr. Emmer also noted that toe clipping is not discussed in the IACUC policy pertaining to genotyping. The IACUC agreed that the IACUC Policies "Rodent Identification" and "Tissue Harvesting for Rodent Genotyping" should be reexamined and revised as necessary. Dr. Emmer will examine the policies and return any recommended revisions for Committee review at the next IACUC meeting. The Committee also advised Dr. Telang to request that the Principal Investigator provided further justification, including why identification at the age proposed is necessary, and inform the PI that the IACUC is

currently reviewing its policies on toe clipping to ensure they conform with current NIH guidelines and reflect best practice.

V. Old Business

A. Follow Up Report: *Proposal* 20706, "Model development for emerging human coronaviruses in the ferret" (*Powell, Emmer*) – *No Report Expected*
There is no update at this time; the IACUC has not yet received a follow-up report from the investigator. None has been expected yet as they have not completed another study.

B. Humane Endpoints Proposal 19657 (*Pantalos*) – *No Report Expected*
There is no update at this time; the IACUC has not yet received a follow-up report from the investigator. The Committee decided to send a letter to the investigator requesting a status update.

VI. New Business

A. Fall 2020 Semi-Annual Inspections (*Sherwood*)
The Committee discussed the upcoming semiannual self-assessment and adjustments that may be necessary due to the current coronavirus pandemic. The IACUC agreed that inspections will consist of only those mandated by regulations to limit potential personnel exposure during the pandemic. The Fall 2020 inspections will include, in addition to the animal facilities, all locations where: surgeries (survival or non-survival) occur; non-USDA species are housed for more than 24 hours; or USDA-regulated species are maintained for more than 12 hours.

The Committee also discussed conducting inspections in accordance with the room capacity limits, especially in Core areas. The IACUC agreed that, in such areas, the inspection team may consult with the laboratory representative via telephone while inspecting the location.

*A motion to accept this course of action was **unanimously approved** (12 "in favor," none opposed, no abstentions).*

[Dr. Telang left the meeting following this discussion; voting member count = 11]

B. NIH Guide Notice Public Comments on Implementation of the Updated AVMA Guidelines for the Euthanasia of Animals: 2020 Edition (*Sherwood*) (**Attachment 7**)
Dr. Sherwood shared this notice for the Committee's information. The Committee requested that the IACUC Office email investigators another reminder about ensuring updated euthanasia signage is posted.

C. FOIA Request – PETA (*Sherwood*) (**Attachment 8**)
Dr. Sherwood informed the Committee about a recent public records request from PETA. The Committee agreed that it should be apprised of all official responses to public records requests pertaining to animal research at the University of Louisville. The IACUC determined that a letter should be sent to Sherri Pawson, Sr. Compliance Officer, formally requesting a copy of the formal response to PETA, as well as a copy of all future official responses to public record requests regarding the university's animal research program.

VII. Adjournment

The IACUC was reminded that the next meeting will occur via teleconference Thursday, 20 August 2020 at 9:00 a.m. *Meeting was adjourned at 10:52 AM.*

Investigator	Protocol	Original Approval	Submission Approval	Expiration	Species	Pain Class	Animals Approved
Pantalos, George	IACUC 17027	2017-09-05 00:	2020-07-31 00:	2020-09-04 00:	Pig (Domestic)	2	102
Modification					**Reviewer:**	LeBlanc, Amanda J	
Porcine Model Lung Harvest for Ex Vivo Lung Perfusion and Preservation							
Wysoczynski, Marcin	IACUC 17080	2019-05-13 00:	2020-08-03 00:	2022-05-12 00:	Mouse (Laboratory)	2	4180
Modification					**Reviewer:**	Pantalos, George	
Innate immunity in heart repair							
Kosiewicz, Michele M	IACUC 17107	2017-09-12 00:	2020-08-03 00:	2020-09-11 00:	Mouse (Laboratory)	2	2795
Modification					**Reviewer:**	Pantalos, George	
Sex-based differences in regulatory T cell responses							
Kosiewicz, Michele M	IACUC 17107	2017-09-12 00:	2020-07-24 00:	2020-09-11 00:	Mouse (Laboratory)	2	2174
Modification					**Reviewer:**	Pantalos, George	
Sex-based differences in regulatory T cell responses							
Bagaitkar, Juhi A	IACUC 17110	2018-07-03 00:	2020-08-18 00:	2021-07-02 00:	Mouse (Laboratory)	2	1836
Modification					**Reviewer:**	Pantalos, George	
Studies looking into the role of NADPH oxidase in modulation host inflammation via differential interactions with periodontal pathogens and apoptotic cells							

Investigator	Protocol	Original Approval	Submission Approval	Expiration	Species	Pain Class	Animals Approved
Tyagi, Neetu	IACUC 17152	2018-01-11 00:	2020-08-03 00:	2021-01-10 00:	Mouse (Laboratory)	2	330
Modification					**Reviewer:**	Pantalos, George	
Mechanisms of mitochondrial dysfunction in brain vasculature							
Cai, Lu	IACUC 17167	2018-03-07 00:	2020-08-14 00:	2021-03-06 00:	Mouse (Laboratory)	2	2522
Modification					**Reviewer:**	Pantalos, George	
Nfr2 activator to prevent diabetic cardiomyopathy: a potential therapeutic approach							
Warawa, Jonathan M	IACUC 17174	2018-01-11 00:	2020-08-17 00:	2021-01-10 00:	Mouse (Laboratory)	1	2400
Modification					**Reviewer:**	Pantalos, George	
Breeding Protocol							
Cave, Matthew C	IACUC 18220	2018-03-30 00:	2020-08-14 00:	2021-03-29 00:	Mouse (Laboratory)	2	2182
Modification					**Reviewer:**	Pantalos, George	
Halogenated aromatic hydrocarbons worsen obesity/metabolic syndrome							
Cave, Matthew C	IACUC 18220	2018-03-30 00:	2020-07-15 00:	2021-03-29 00:	Mouse (Laboratory)	1	2172
Modification					**Reviewer:**	Pantalos, George	
Halogenated aromatic hydrocarbons worsen obesity/metabolic syndrome							

Investigator	Protocol	Original Approval	Submission Approval	Expiration	Species	Pain Class	Animals Approved
Boakye, Maxwell	IACUC 18232	2018-03-12 00:	2020-07-27 00:	2021-03-11 00:	Pig (Domestic)	2	256
Modification					**Reviewer:** Pantalos, George		

Myelotomy with intramedullary hemorrhagic necrosis removal (MIHN) as a therapeutic strategy in a porcine model of traumatic spinal cord injury

Clark, Barbara J	IACUC 18239	2018-10-04 00:	2020-08-14 00:	2021-10-03 00:	Mouse (Laboratory)	2	456
Modification					**Reviewer:** Pantalos, George		

The role of StarD5 in lipid homeostasis

Boakye, Maxwell	IACUC 18290	2018-07-24 00:	2020-08-17 00:	2021-07-23 00:	Pig (Domestic)	2	21
Annual Review					**Reviewer:** Magnuson, David S, Ph.D.		

Improving Outcomes Using Myelotomy with Intramedullary Hemorrhagic Necrosis Removal in Porcine Model of Acute Thoracic Cord Injury

Bickford, Martha E	IACUC 18295	2018-08-24 00:	2020-07-15 00:	2021-08-23 00:	Mouse (Laboratory)	2	1653
Modification					**Reviewer:** Pantalos, George		

Functional Organization of the Mouse Visual Thalamus

Ng, Chin K	IACUC 18304	2018-10-22 00:	2020-08-17 00:	2021-10-21 00:	Calf	1	0
Annual Review					**Reviewer:** Corbitt, Cynthia, Ph.D.		

Renewal of Core Animal Laboratory: MRI Imaging of Laboratory Animals Bovine

Investigator	Protocol	Original Approval	Submission Approval	Expiration	Species	Pain Class	Animals Approved
Gobejishvili, Leila	IACUC 18356	2019-01-09 00:	2020-07-24 00:	2022-01-08 00:	Mouse (Laboratory)	2	3366
Modification					**Reviewer:**	Pantalos, George	
The role of cAMP/PDE4 in liver injury and fibrosis							
Mohamed, Tamer M	IACUC 18402	2019-01-10 00:	2020-07-31 00:	2022-01-09 00:	Mouse (Laboratory)	2	1820
Modification					**Reviewer:**	Pantalos, George	
Study Novel approaches for cardiac regeneration in vivo							
Kirpich, Irina	IACUC 18418	2019-01-09 00:	2020-07-15 00:	2022-01-08 00:	Mouse (Laboratory)	3	2160
Modification					**Reviewer:**	Pantalos, George	
The role of dietary fat in alcoholic liver disease							
Tang, Xian-Liang	IACUC 19469	2019-07-24 00:	2020-08-18 00:	2022-07-23 00:	Rat (Laboratory)	2	644
Modification					**Reviewer:**	Pantalos, George	
Cardiac function, survival and repair after myocardial infarction in rats							
Tang, Xian-Liang	IACUC 19469	2019-07-24 00:	2020-08-18 00:	2022-07-23 00:	Rat (Laboratory)	2	644
Modification					**Reviewer:**	Pantalos, George	
Cardiac function, survival and repair after myocardial infarction in rats							

Investigator	Protocol	Original Approval	Submission Approval	Expiration	Species	Pain Class	Animals Approved
Tang, Xian-Liang	IACUC 19469	2019-07-24 00:	2020-08-18 00:	2022-07-23 00:	Rat (Laboratory)	2	644
Modification					**Reviewer:**	Pantalos, George	
Cardiac function, survival and repair after myocardial infarction in rats							
Conklin, Daniel	IACUC 19534	2019-10-17 00:	2020-08-03 00:	2022-10-16 00:	Mouse (Laboratory)	2	5256
Modification					**Reviewer:**	Pantalos, George	
General Inhalation Protocol							
Howland, Dena R	IACUC 19543	2019-08-02 00:	2020-08-14 00:	2022-08-01 00:	Cat	2	475
Modification					**Reviewer:**	Pantalos, George	
Altered Motor Function & Force Feedback After Spinal Cord Injury and Force Feedback Redistribution & Eccentric-Focused Rehab post-SCI							
Damodaran, Chendil	IACUC 19565	2019-10-16 00:	2020-07-17 00:	2022-10-15 00:	Mouse (Laboratory)	2	732
Modification					**Reviewer:**	Pantalos, George	
Copy of Targeting AR and Akt for the Treatment of Prostate Cancer							
Damodaran, Chendil	IACUC 19565	2019-10-16 00:	2020-08-18 00:	2022-10-15 00:	Mouse (Laboratory)	2	810
Modification					**Reviewer:**	Pantalos, George	
Copy of Targeting AR and Akt for the Treatment of Prostate Cancer							

Investigator	Protocol	Original Approval	Submission Approval	Expiration	Species	Pain Class	Animals Approved
Damodaran, Chendil	IACUC 19566	2019-09-23 00:	2020-08-12 00:	2022-09-22 00:	Mouse (Laboratory)	2	1440
Modification					**Reviewer:** Pantalos, George		
Targeting Breast and Bladder Cancer Cells by Small Molecules							
Warawa, Jonathan M	IACUC 19567	2019-10-29 00:	2020-08-18 00:	2022-10-28 00:	Mouse (Laboratory)	3	3210
Modification					**Reviewer:** Pantalos, George		
Infectivity of Burkholderia species in mice							
Siskind, Leah J	IACUC 19568	2019-10-28 00:	2020-08-05 00:	2022-10-27 00:	Mouse (Laboratory)	3	1127
Modification					**Reviewer:** Pantalos, George		
Role of ceramides in acute kidney injury							
Tang, Xian-Liang	IACUC 19615	2019-11-22 00:	2020-08-10 00:	2022-11-21 00:	Pig (Domestic)	2	185
Modification					**Reviewer:** Pantalos, George		
Myocardial protection and regeneration after infarction							
Severson, William E	IACUC 19625	2020-01-24 00:	2020-08-17 00:	2023-01-23 00:	Mouse (Laboratory)	3	1800
Modification					**Reviewer:** Pantalos, George		
Screening of antivirals for SARS-CoV in mice							
Lawrenz, Matthew B	IACUC 19632	2019-10-23 00:	2020-08-14 00:	2022-10-22 00:	Mouse (Laboratory)	1	1344
Modification					**Reviewer:** Pantalos, George		

Investigator	Protocol	Original Approval	Submission Approval	Expiration	Species	Pain Class	Animals Approved
Mouse breeding colony							
Tyagi, Suresh C	IACUC 20695	2020-03-17 00:	2020-07-24 00:	2023-03-16 00:	Mouse (Laboratory)	2	632
Modification					**Reviewer:**	Pantalos, George	
Copy of Reversing Skeletal Muscle Myopathy by Hydrogen Sulfide							
Severson, William E	IACUC 20706	2020-02-28 00:	2020-07-20 00:	2023-02-27 00:	Ferret	3	91
Modification					**Reviewer:**	Pantalos, George	
Model development for emerging human coronaviruses in the ferret							
Severson, William E	IACUC 20706	2020-02-28 00:	2020-08-17 00:	2023-02-27 00:	Ferret	3	117
Modification					**Reviewer:**	Pantalos, George	
Model development for emerging human coronaviruses in the ferret							
Severson, William E	IACUC 20706	2020-02-28 00:	2020-08-07 00:	2023-02-27 00:	Ferret	3	117
Modification					**Reviewer:**	Pantalos, George	
Model development for emerging human coronaviruses in the ferret							
Severson, William E	IACUC 20706	2020-02-28 00:	2020-08-03 00:	2023-02-27 00:	Ferret	3	91
Modification					**Reviewer:**	Pantalos, George	
Model development for emerging human coronaviruses in the ferret							
Bodduluri, Haribabu	IACUC 20725	2020-06-19 00:	2020-08-07 00:	2023-06-18 00:	Mouse (Laboratory)	1	1650
Admin Mod - strain addition					**Reviewer:**	Tulloch, Tegan N	

Investigator	Protocol	Original Approval	Submission Approval	Expiration	Species	Pain Class	Animals Approved
Core Animal Laboratory: Functional Microbiomics Core Facility (Germ-Free/Gnotobiotic Mouse Facility)							
Ding, Jixiang	IACUC 20729	2020-07-29 00:	2020-07-29 00:	2023-07-28 00:	Mouse (Laboratory)	1	300
3YR					**Reviewer:**	Corbitt, Cynthia, Ph.D.	
Copy of Genetic control of mouse craniofacial development and malformation							
Steinbach Rankins, Jill M	IACUC 20735	2020-07-28 00:	2020-07-28 00:	2023-07-27 00:	Mouse (Laboratory)	2	180
3YR					**Reviewer:**	LeBlanc, Amanda J	
Copy of Understanding the Host-Microbiome-Therapeutic Triad: Implications for Designing Alternative Intravaginal Delivery Platforms to Treat Bacterial Vaginosis							
Severson, William E	IACUC 20743	2020-04-21 00:	2020-07-16 00:	2023-04-20 00:	Hamster, Syrian	3	1632
Modification					**Reviewer:**	Pantalos, George	
Coronavirus disease in hamsters for antiviral testing							
Carll, Alex P	IACUC 20764	2020-08-14 00:	2020-08-14 00:	2023-08-13 00:	Mouse (Laboratory)	2	7296
3YR					**Reviewer:**	LeBlanc, Amanda J	
Air Pollution and Heart Failure							
Shao, Hui	IACUC 20765	2020-08-05 00:	2020-08-05 00:	2023-08-04 00:	Mouse (Laboratory)	2	2221
3YR					**Reviewer:**	Telang, Sucheta	
Innate immunity in the adaptive T cell mediated autoimmune uveitis in the animal models							

Investigator	Protocol	Original Approval	Submission Approval	Expiration	Species	Pain Class	Animals Approved
Kaufman, Christina L	IACUC 20771	2020-08-06 00:	2020-08-06 00:	2023-08-05 00:	Rat (Laboratory)	2	328
Initial Review					**Reviewer:** Clark, Geoff		
Effect of Peritransplant C3d blockade and Ischemia on chronic rejection and Vasculopathy in an Experimental OMC Flap Model of VCA							
O'Toole, Timothy E	IACUC 20772	2020-07-27 00:	2020-07-27 00:	2023-07-26 00:	Mouse (Laboratory)	2	3436
3YR					**Reviewer:** LeBlanc, Amanda J		
Endothelial Progenitor Cells and Particulate Air Pollution							
Hubscher, Charles H	IACUC 20773	2020-07-16 00:	2020-07-16 00:	2023-07-15 00:	Rat (Laboratory)	2	135
3YR					**Reviewer:** Samuelson, David J, Ph.D.		
Copy of Development of a comprehensive assessment of bowel function after SCI? / Effects of Activity-Dependent Plasticity on Bowel Function After Spinal Cord Injury							
Li, Junling	IACUC 20778	2020-08-14 00:	2020-08-14 00:	2023-08-13 00:	Mouse (Laboratory)	3	80
Initial Review					**Reviewer:** Magnuson, David S, Ph.D.		
Pilot study to assess PET imaging in TBI							
Conklin, Daniel	IACUC 20781	2020-08-14 00:	2020-08-14 00:	2023-08-13 00:	Mouse (Laboratory)	2	6234
3YR					**Reviewer:** LeBlanc, Amanda J		
Cardioprotective Mechanisms of Glutathione S-transferase P							
Li, Junling	IACUC 20783	2020-08-03 00:	2020-08-03 00:	2023-08-02 00:	Mouse (Laboratory)	3	288
Initial Review					**Reviewer:** LeBlanc, Amanda J		
Imaging Klebsiella pneumoniae (Kp) infection using 18F-fluorodeoxysorbitol (FDS) in mice							

Investigator	Protocol	Original Approval	Submission Approval	Expiration	Species	Pain Class	Animals Approved
Bodduluri, Haribabu	IACUC 20786	2020-07-23 00:	2020-07-23 00:	2023-07-22 00:	Mouse (Laboratory)	2	12
Initial Review					**Reviewer:**	Magnuson, David S, Ph.D.	

Bleomycin administration to germ-free mice

Hood, Joshua L	IACUC 20792	2020-08-17 00:	2020-08-17 00:	2023-08-16 00:	Mouse (Laboratory)	2	252
Initial Review					**Reviewer:**	Samuelson, David J, Ph.D.	

Extracellular Vesicle-based immunotherapy for hepatocellular carcinoma

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Diamond, Gill	IACUC 20797	2020-07-17 00:	2020-07-17 00:	2023-07-16 00:	Tissue Only	Tissue Only	
Tissue					**Reviewer:**	Pantalos, George	

Innate Immune Mechanisms of Periodontal Disease and Inflammatory Bowel Disease

University of Louisville

Institutional Animal Care and Use Committee

Policies and Procedures

Field Investigations

Policy: An IACUC *Proposal* must be completed and approved prior to commencing *any* form of field investigation utilizing vertebrate animals. A *Field Investigation* is defined as a study conducted on wild (non-domesticated) vertebrate animals in their natural habitat or in confinement that may or may not involve an invasive procedure, harm, or materially alter or influence the behavior or activities of an animal under study. Investigators should not only complete the section of the IACUC *Proposal* that deals specifically with field investigations but also other general sections of the IACUC as applicable. In addition to specific target species and information concerning proposed procedures and activities, the IACUC *Proposal* must also demonstrate knowledge of relevant zoonotic diseases, associated safety issues, and any laws or regulations that apply.

Rationale: To comply with the United States Department of Agriculture (USDA) through the Animal Welfare Act (AWA), PHS *Policy on the Humane Care and Use of Laboratory Animals*, and the *Guide for the Care and Use of Laboratory Animals* (*Guide*), all studies that involve vertebrate animals require IACUC oversight. This oversight extends to studies conducted on wild (non-domesticated) animals in their natural habitat or in confinement, and applies the basic principles of humane care as outlined for studies conducted in the laboratory. In addition, the *Guide* charges the institution's health and safety officials to review occupational health and safety issues associated with proposed studies and supply the IACUC with assurances that the field investigation does not compromise the safety of either animals or persons in the field. The IACUC *Proposal* can also serve as an evaluation of the scientific merit of the proposed study which may be required for various permits needed to perform field studies.

Both writing and reviewing a *Proposal* utilizing non-domesticated species provides a unique challenge to both investigators and IACUC members due to the large number of unique species that could be the subject of a field investigation, limited information on techniques and medications for many species, uncertainty of the effects of experimentation on wildlife, the limitations presented by a field setting that may dictate different standards than those accustomed in a controlled lab setting, and occupational hazards. This policy and its associated information sheet (*see:* IACUC Information Sheet "Field Studies") serve as a guide to researchers and IACUC members in the drafting and reviewing of *Proposals* involving field investigations on non-domesticated vertebrate animals.

Procedures, Guidelines, and Exceptions:

1. Investigators conducting any form of field investigation, including observation-only studies, must submit an IACUC *Proposal* for review and approval prior to initiating the study. The UofL IACUC requires that a *Proposal* be submitted for any and all types of field studies, even those that are only observational in nature.
2. The PI must report to the IACUC any unexpected animal injuries or deaths due to activities associated with the research project as an adverse event as per IACUC policy "*Unexpected Findings and Adverse Events*".

Original Adoption: 20 August 2020

3. Principal Investigators are strongly encouraged to consult with a qualified wildlife biologist prior to the submission of a *Proposal* and should reference such consultations within the *Proposal*. Investigators should also consult the *Guide for the Care and Use of Laboratory Animals* and relevant professional societies and available guidelines (*see:* IACUC Information Sheet "Field Studies").
4. Principal Investigators are responsible for complying with all local, state, federal and international laws and regulations. It is the responsibility of the PI to obtain all necessary permits *prior* to the start of research and to include relevant permit information within the IACUC *Proposal*. Copies of permits must be made available upon request of the IACUC. All pertinent permit details (federal, state and site specific) should be included in the IACUC *Proposal*.
5. All personnel, including students or volunteers who will participate in field research, must be listed on the *Proposal* form. Project participants, personnel training, protective equipment, and associated safety issues or risks (e.g., zoonotic disease contraction, injury, etc.) are subject to Occupational Health and Safety Program review and approval.
6. Investigators must document the number of animals used and report animal usage to the IACUC Office annually (note: this applies to non-observation field studies only).
7. Method(s) of euthanasia or release must be described in the IACUC *Proposal*. Methods of euthanasia must comply with IACUC Policy (*see:* "Euthanasia of Research Animals") and the AVMA *Guidelines for Euthanasia*. Information should also include the method of euthanasia that will be used for target and non-target species as part of planned experiment or due to unexpected injury or outcome, even if not anticipated (E.g., broken wings, hyperthermia, and seizure).
8. Animals held or housed must be monitored *at least daily* for applicable factors such as appearance, activity level, general behavior, appetite, rate of growth, change in body weight/body condition, breeding success, etc. Documentation of observations and housing parameters must be maintained for a period of three years and available for IACUC inspection at all times. The duration and location that animals will be held in captivity must be included in the IACUC *Proposal* for review and approval.

References:

1. *Animal Welfare Act and Animal Welfare Regulations, as amended. Title 9 CFR Subchapter A - Animal Welfare, Parts 1, 2, and 3.* USDA Animal and Plant Health Inspection Service. Current Edition.

2. *AVMA Guidelines for the Euthanasia of Animals: 2020 Edition.* (https://www.avma.org/sites/default/files/2020-01/2020-Euthanasia-Final-1-17-20.pdf)

3. National Research Council, *Guide for the Care and Use of Laboratory Animals*, 8th Ed., National Academy Press, Revised 2011.

4. *Field Studies and the IACUC: Protocol Review, Oversight, and Occupational Health and Safety Considerations*. K. Laber, B. Kennedy, L. Young. Lab Animal Volume 36 No. 1 January 2007.

5. National Institutes of Health. 2002. Public Health Service Policy on Humane Care and Use of Laboratory Animals. NIH Office of Laboratory Animal Welfare, Bethesda

6. Interagency Research Animal Committee (IRAC). 1985. *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training.*

Original Adoption: 20 August 2020

Information Sheet

Research Services
Institutional Animal Care and Use Committee
Comparative Medicine Research Unit

Field Studies

An IACUC *Proposal* must be completed and approved prior to commencing any form of field investigation utilizing vertebrate animals. This document is meant to serve as a resource for Principal Investigator's and IACUC members.

Professional Society Guidelines and other Sources:

To prepare and evaluate *Proposals*, researchers and IACUC members should consult with experts and refer to professional society guidelines which are useful tools to reference current approaches to field practices. However, such guidelines may deviate from current regulatory policies and require written justification within the IACUC by the principle investigator.

Current applicable guidelines include the below listed references.

a) American Society of Mammalogists*: Guidelines of the American Society of Mammalogists for the use of wild mammals in research and education*

b) Ornithological Council: *Guidelines to the Use of Wild Birds in Research.*

c) American Fisheries Society, American Institute of Fishery Research Biologists, and American Society of Ichthyologists and Herpetologist: *Guidelines for the Use of Fishes in Research.*

d) American Society of Ichthyologists and Herpetologists: *Guidelines for the Use of Live Amphibians and Reptiles in Field and Laboratory Research.*

e) Field euthanasia for Wild life 2018, NIH OLAW https://olaw.nih.gov/education/educational-resources/webinar-2018-03-28.htm

Experimental Groups and Pain/Distress Classification:

- Principal Investigators are responsible for complying with all local, state, federal and international laws and regulations. Permits should be obtained prior to the start of research and details should be provided within the *Proposal*. Copies of permits must be made available upon request of the IACUC.
- A description of experimental groups should be provided in the *Proposal* summarizing exactly what will happen to each animal and when. The appropriate pain and distress classification should be assigned to each group. The American Society of Mammologists/Ornithological Council position and addendum #3 cite the following activities as potential pain class I studies:
  - Properly functioning, appropriately placed live traps or nets designed to simply hold an animal without injury until removal provided the traps/nets are checked frequently and the individuals are adequately training in setting the devices and removing the animals.
  - Tissue sampling and marking techniques utilizing procedures that are not more invasive than peripheral blood sampling and involve no or only momentary or slight pain.

Justification of Animal Numbers:

- Estimating and evaluating the number of animals that may be involved in a field investigation may pose a challenge. There may be cases in which the number of animals to be used is unknown as it depends on collection opportunities, the numbers of animals may be justifiably large (perhaps an entire population in some studies), or very limited such as tracking of elusive species. In such cases citations for the numbers of animals used previously in similar activities, seeking input from a qualified statistician, and/or estimates derived from population densities may be useful

Field Study: Species

- Targeted and non-targeted (incidental capture) species should be described, including estimated number of animals.

Field Study: Location

- A detailed description of the study site(s) where the field studies will be conducted should be provided. If applicable, photographs or videos that document specific aspects of the site(s) should be included.

Field Study: Capture and Handling

- The methods of animal capture and handling should be fully described, including the potential short- and long-term effects on animals, and details addressing:
  - How will the animals be captured? Include the type and size of trap.
  - For studies involving recapture, the expected time period between captures should be included.
  - How will researchers minimize the potential harm caused to the animal by the traps?
  - What is the frequency of checking traps?
  - Are there any precautions in place for preventing capture of non-target species?
  - What happens to non-target species if captured?
  - Comment on any expected injury and mortality due to trapping.
  - While in the trap, is the animal appropriately sheltered and protected from predators and the elements?
  - Describe how the target and non-target species will be handled include methods to minimize distress.
  - Does handing have the potential to cause rejection by conspecifics if released?
  - Does handing have the potential to cause decreased survivability if released?

Field Study: Animal Holding/Housing

- The duration of time animals will be held in captivity prior to euthanasia or release should be described, including:
  - The location and duration of housing.
  - Description of caging size (LxWxH) and materials constructed from.
  - How does the caging system support the biological needs of the animal? Note that the design of enclosures and methods of care must accommodate salient features of the animal's ecology, morphology, physiology, and behavior.
  - Will other species be housed or held in the same facility?
  - What are the nutritional requirements and how will they be met? Nutritionally balanced diets must be provided, or natural foods should be duplicated as closely as possible.
  - What are the water requirements and how will they be met?
  - What are the ventilation and temperature requirements and how will they be met?
  - Natural light, ventilation, temperature, and humidity conditions should be provided, unless these are factors under investigation.
  - Include information on providing those aspects of the natural habitat deemed important to the survival and well-being of the animals
  - Will animals be single housed and/or isolated from conspecifics?
  - What enrichment will be provided for the animal(s) while being housed in the lab or in captivity?
- Animals held or housed must be monitored *at least daily* for applicable factors such as appearance, activity level, general behavior, appetite, rate of growth, change in body weight/body condition, breeding success, etc. Documentation of observations and housing parameters must be maintained for a period of three years and available for IACUC inspection at all times.

- Newly captured animals that are brought to the laboratory should be quarantined from resident animals. Investigators should refer to IACUC policy "*Animal Security in Investigators Laboratories*" for additional security measures.
- Housing may require collection permits from various agencies.

Field Study: Transportation

- If animals will be transported from the capture site, details of transportation should be fully described and include:
  - Describe the method of transportation (e.g., private vehicles, commercial services, etc.).
  - Describe the transport enclosure, including dimensions (LxWxH) and construction material.
  - Estimated time in transit.
  - Describe animal care in transit (e.g., food/water provided, bedding, temperature control, etc.).
  - Describe measures in place to prevent escape.
  - Will the animal be exposed to other animals during transit?

Field Study: Population Impact

- Describe any anticipated impact on local populations of target and non-target species.
  - If the target species is endangered, you should include that information here.

Field Study: Permits

- Principal Investigators are responsible for complying with all local, state, federal and international laws and regulations. Permits should be obtained prior to the start of research and details should be provided within the *Proposal*. Copies of permits must be made available upon request of the IACUC.
  - **Federal and State permits**: If your research requires federal or state permits, it is unlawful to begin work until all permits have been obtained. You may not start the work for which permits are required until the permits are issued, even if your *Proposal* has been approved.
  - **Permits required by other agencies**: If applicable, must be stated in the *Proposal* and obtained prior to conducting the study.
  - Other permit considerations:
    - Each state has its own requirements for collecting, housing, sampling, displaying, and generally using wildlife.
    - When animals or their tissues are moved between states, each state's fish and game agency (or department of natural resources), including wildlife preserves and refuges, should be consulted for compliance with specific policies and regulations.
    - When animals or animal tissues are imported from another country, several agencies should be contacted to ensure that necessary permits and precautions are taken. Common regulatory agencies that oversee the collection and handling of wildlife include the United States Fish and Wildlife Service, the Department of the Interior (specifically in terms of the Convention on International Trade in Endangered Species of Wild Fauna), the United States Department of Agriculture Animal and Plant Health Inspection Service (for protection against importing animal pathogens), and the Centers for Disease Control and Prevention (CDC) (for protection against importing human pathogens).
    - Other relevant federal legislation includes: the Lacey Act, which pertains to movement of wild mammals or parts thereof to non-designated ports of entry and anything related to injurious wildlife that could cause environmental or agricultural damage; the Marine Mammal Protection Act, which regulates the harassment and handling of all marine mammal species; the Migratory Bird Act, which regulates the

handling and banding of migratory bird species; and the Endangered Species Act of 1972.

Field Study: Occupational Health and Safety Considerations

- Principal Investigators should be knowledgeable about relevant zoonotic diseases and associated safety issues (e.g., traumatic injuries, use of venomous species). This section should detail:
  - Potential risks including: location associated risks (e.g., weather, terrain, remoteness, insect, poisonous plants, etc.); risk of injury (e.g., bites, kicks, needle stick, restrain and capture injury, etc.); and risk of contracting zoonotic disease.
  - Methods of training personnel.
  - Other methods to ensure personnel safety.

Procedures:

- All procedures to be performed and manipulations of animals should be described. The following should be given consideration when planning procedures:
  - Methods used for sampling tissues or specimens from wild animals should be designed to obtain the maximal amount of scientific data, with the least amount of animal handling, restraint, and distress, involving a minimum number of animals.
  - Aseptic sampling techniques and surgical procedures must be utilized.
  - Researchers must consider whether antimicrobial drugs should be administered following sampling or surgical procedures.
  - Methods that cause more than slight or momentary pain or discomfort require the use of appropriate anesthetics and/or analgesics.

Analgesia and Anesthesia:

- Very little information exists concerning the pain perception in many species potentially studied in a field investigation. According to IRAC principle four “Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals." Because information concerning appropriate anesthesia and analgesia regimes, doses, and routes may be limited, Professional Society Guidelines, veterinarians, and experts in the field should be consulted to determine the best application. Investigators should explain how the animal will be monitored and supported until fully recovered from any anesthesia provided.
- In addition to individual animal pain and distress, special consideration should be given to the following questions:
  - Could anesthesia facilitate less stressful and safer handling?
  - Are there legal requirements for use of the proposed agent in a field setting?
  - What is the probability the agent will enter the food chain and affect other species?

Euthanasia and/or Final Disposition:

- Method(s) of euthanasia or release must be described in the “Euthanasia or Other Disposition” section of the IACUC proposal.
- Information should also include the method of euthanasia that will be used for target and non-target species as part of planned experiment or due to unexpected injury or outcome, even if not anticipated (E.g., broken wings, hyperthermia, and seizure). All methods should comply with AVMA *Guidelines for Euthanasia* and any exceptions must be justified. Any carcass that has the potential to negatively impact surrounding wildlife (chemicals injected) should be disposed of in a way to prevent impact on surrounding wildlife (e.g., Bury deeply, landfill, incinerate.)

- Whenever practical, ecologically appropriate, and in accordance with any applicable laws and regulations, wild-caught animals should be released as soon as possible after capture at the site of original capture if: their ability to survive has not been impaired; they can be expected to function normally; conditions are conducive to their survival; their release is not likely to spread pathogens; and the release will not be detrimental to the well-being of the existing native animals. The release of animals held in captivity for more than a short period of time should be considered carefully to minimize potential impact on the local population and stress to the released individual. See: *Guidelines of the American Society of Mammalogists on the Use of Wild Mammals in Research.*

Alternatives to Painful Procedures:

- This section should clearly demonstrate that the methods proposed are the best practice as determined by applicable Professional Society Guidelines and pertinent literature searches. The following potential distresses should also be addressed:
  - Does any of the procedures to be performed increase the likelihood of predation or ability to compete?
  - Does the procedure have the potential to cause rejection by conspecifics?
  - Is research occurring during timeframe when target species is likely to have independent young? Could young animals be negatively impacted due to capture of care giving adults?

Institutional Animal Care and Use Commit

From: Warawa,Jonathan Mark
Sent: Monday, July 20, 2020 2:03 PM
To: Institutional Animal Care and Use Commit
Cc: Pantalos,George; Sherwood,Leslie C
Subject: RE: IACUC 19567 Follow Up

Tegan,
We haven't forgotten about this request. This is custom equipment and I have been working with the vendor of the digital equipment side on the best way to calibrate our system. We have archived data which we have to analyze in retrospect. I think we are close to settling on the best way to do this, and we hope to then have a dataset for the IACUC in the next couple of weeks.
Best,
Jon

Jonathan Warawa, PhD
Associate Professor
Department of Microbiology and Immunology
Center for Predictive Medicine for Biodefense and Emerging Infectious Disease
[redacted]
University of Louisville
Louisville, KY 40202
Phone (502) 852-5558
Fax (502) 852-5468
jonathan.warawa@louisville.edu

From: Institutional Animal Care and Use Commit <iacuc@louisville.edu>
Sent: Monday, July 20, 2020 1:44 PM
To: Warawa,Jonathan Mark <jonathan.warawa@louisville.edu>
Cc: Pantalos,George <george.pantalos@louisville.edu>; Sherwood,Leslie C <leslie.sherwood@louisville.edu>
Subject: IACUC 19567 Follow Up
Importance: High

Good Afternoon Dr. Warawa,

Please see the attached letter from the IACUC in regard to your Proposal 19567. If you have any questions, please let us know.

Best Regards,

Tegan

Center for Predictive Medicine
for Biodefense and Emerging Infectious Diseases
UNIVERSITY OF
LOUISVILLE

August 13, 2020

Institutional Animal Care and Use Committee
University of Louisville

Dear IACUC,

This letter is being submitted to report an adverse event that occurred to one animal associated with procedures approved in Protocol 19625. The study began on 7/21/2020 with animals being monitored twice daily and body weight recorded once daily for health checks/endpoint criteria as per protocol. At the Day 6 (7/27/20) morning health check, a mouse was found in the weighing vessel on the balance in the biosafety cabinet in the procedure room of the vivarium. The animal did not have access to food or water while in the weighing vessel. Research staff reported that the mouse was in poor condition and therefore it was immediately euthanized.

Upon investigation, the access activity report for the vivarium on 7/26/20 indicate the research staff completed their health checks/daily weights at approximately 9:00 am followed by RRF staff performing husbandry duties and health checks of the mice at approximately 10:15 am. There was no PM check performed.

Several errors occurred that resulted in the animal being left in the weighting vessel without food and water from 9:00 AM 7/26/20 until found in the AM of 7/27/20.

1. The research staff performing AM checks on 7/26/20 found that no animals met endpoint criteria but, after weighting, did not return the animal to its home cage. This was a result of failing to follow proper practices. If the SOP had been followed, they would have found the mouse in the weighing vessel since the protocol states that weighing vessel should be cleaned after weighing each mouse. Additionally, the biosafety cabinet is to be cleaned at the conclusion of all procedures and prior to exiting the room.

2. RRF staff did not accurately count the animals in the cages on 7/26/20. The SOP associated with Work Practice Controls indicates that the number of animals in the cage will be reconciled with the number indicated on the cage card. There was an obvious discrepancy that was not recognized.

3. Research staff did not perform a PM health check. On 7/24/20 the research staff member that was to perform the weekend AM and PM checks suffered a serious injury and was unable to be at work. This left other staff members covering the checks on very short notice. We feel this was the main factor for the PM checks being mistakenly missed on 7/26/20.

[redacted] Louisville, KY 40222; Phone: 502-852-1339; Fax: 502-852-1393
[redacted] Louisville, KY 40202; Phone: 502-852-5596; Fax: 502-852-5468

The incident was reported immediately to Dr. Powell and Ms. Cowan, the ARO/BSO. Also Dr. Warawa was briefed, since he is officially the involved research staff's direct supervisor.

Corrective Actions:

1. Retraining of research staff is required on SOPs AC-04-01-XX: Mouse Husbandry: ABSL3 and AC-02-04-XX: Routine disinfection of ABSL2/3 anterooms, corridors, animal holding and procedure rooms. Furthermore, the research staff has been given a warning.

2. Retraining of RRF staff on SOP AC-04-00-XX Work Practice Controls has been completed.

Unfortunately the combined oversights led to a very regretful outcome for this animal. We are disturbed by this event and acknowledge that mistakes were made by both of our staffs. We feel we have taken appropriate actions to prevent any additional future incidents through retraining but welcome additional suggestions/requirements by the committee.

Sincerely,

William E. Severson, Ph.D.
Director of Shared Resources
Center for Predictive Medicine
Regional Biocontainment Laboratory
University of Louisville
Phone: 502.852.1546

Karen Powell, DVM, Ph.D
Staff Veterinarian Comparative Medicine Research Unit
Supervisor Large Animal Clinical Services
& Regional Biocontainment Laboratory
Assistant Professor University of Louisville School of Medicine
Phone: 502.852.7051

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

24 April 2019

Dr. Jonathan Warawa, Dr. Matthew Lawrenz
Department of Microbiology & Immunology
Center for Predictive Medicine
University of Louisville
Louisville, KY 40202

Dear Drs. Warawa and Lawrenz:

The IACUC discussed the subcommittee's report and recommendations at its convened meeting of 18 April 2019. First and foremost, the IACUC thanks you for taking the time to meet with the Committee and subcommittee and provide additional information on your humane endpoints.

Contingent upon the IACUC's understanding that you will be conducting studies with a new experimental design based on evaluating bacterial load which will minimize pain and distress of animals enrolled in the pseudomonas studies more so than the currently designed studies, the IACUC has agreed that the following humane endpoints with clarification are acceptable and that you will modify your existing IACUC *Proposals*, and write any future IACUC *Proposals*, to incorporate:

1. Body temperature humane endpoint of 80.5ºF
2. Clarify that animals will be checked by CPM staff at 8 hour time intervals ***only***, and animals will be euthanized at these time points checks if humane endpoints are met; if RRF faculty/staff identify an animal(s) during their checks between the CPM 8 hour time point checks that meet(s) the humane endpoint criteria, then the RRF will notify the PI and the animals will be euthanized as soon as possible.
3. Justification for only checking the animals every 8 hours should be included in the IACUC *Proposal* modification (i.e., current humane endpoint established such that x% of animals will survive to the next 8 hour time point, increasing the frequency of animal health checks as the animals near the body temperature humane endpoint would add additional stress to the animals and result in a decrease in statistical power therefore requiring additional numbers of animals, and include anything else you can add to strengthen the justification).

Again, the IACUC recognizes and greatly appreciates your time, effort, and attentiveness in resolving this situation. Please contact either myself or Dr. Sherwood if you have any questions or concerns.

Sincerely,

George Pantalos, PhD
IACUC Chair

University of Louisville · Louisville, KY 40292
P: 502.852.7307 **F:** 502.852.7943

Excerpt from April 2019 IACUC Meeting Minutes:

C. Humane Endpoints Proposals 16579 and 16592 (Pantalos, Sherwood, Hopp, LeBlanc, Palmer, Samuelson, Smith)

The IACUC subcommittee met with Drs. Warawa and Lawrenz last week to review requested data and how the current humane endpoints were established. The subcommittee noted that Dr. Lawrenz is exploring a new experimental design based on evaluating bacterial load which will minimize pain and distress of the animals enrolled in the pseudomonas studies more so than the currently designed studies.