



Memorandum

To: Elizabeth Cantwell, PhD, Senior Vice President, Research & Innovation
From: Institutional Animal Care and Use Committee
Subject: Semi-Annual Report of the Program Review and Facility Inspection
Date: June 13, 2022

This report summarizes the IACUC's results of its most recent program review and facility inspection, as required by the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), Section IV.B.1.-3., the *Guide for the Care and Use of Laboratory Animals (Guide)*, and the Animal Welfare Act (AWA) regulations, as applicable. Submission of semi-annual reports to the Institutional Official is a condition of this institution's Animal Welfare Assurance with the NIH Office of Laboratory Animal Welfare (OLAW).

IACUC Updates/Issues:

- The IACUC and staff continue to develop and implement additional tools and assistance for tracking lab training and have been working with PIs according to the schedule set forth in the Fall 2020 semi-annual programmatic review to assure the IACUC can adequately evaluate the effectiveness of the training programs used by PIs.
 - The Committee and IACUC staff continue to assist PIs in developing appropriate documentation for training, and to emphasize the importance of training to research and animal welfare. A plan was developed in accordance with the Fall 2020 SA programmatic review requirements and has been implemented.
 - Implementation of the specific tools developed by IACUC staff remains intermittent, but PIs have adopted better tracking and documentation of training activities and are increasingly able to produce documentation when requested. Additional information and suggestions are provided as part of the semi-annual inspection process and as part of the PAM program. Associated documents, I-IC-GU-302 Training Documentation, I-IC-SOP-118 Lab Training Documentation, and associated forms and tools were approved by the committee and rolled out to PIs.
 - The IACUC continues to follow recommendations and requirements of federal animal welfare regulations.
- Animal rights organizations have increased activity nation-wide, including at The University of Arizona. Research facilities with animal use will continue to encounter:
 - Increased protests and advertising campaigns with public visibility, and obvious biased information.

- The rise in public awareness of the presence of animal use at universities and research facilities does not necessarily mean a rise in accurate public knowledge and education of the role of animals in scientific and medical inquiry, discovery, and research.
- Increased FOIA and public records requests including an expanded scope of the information being sought.
- National and international organizations that support the use of animals in scientific and medical research do offer public outreach and education. However direct communication, education, and transparency on a more local level would also help in ensuring an accurate and cohesive message is being delivered. The IACUC recommends that the University of Arizona create a public dialogue regarding the importance of animal research and its dedication to animal welfare.
- The Animal Welfare Program office is still in need of a Director, as well as increased support for formal PAM activity.
- Interactions between the various aspects of the Animal Care and Use Program and investigators continue to be favorable. We strive to ensure compliance by emphasizing the positive, educational aspects of the Program, providing resources, standardizing procedures, and being responsive to investigator needs, all within our regulatory framework. Additionally, the program seeks to continue to foster a culture shift that allows us to meet not just the letter of the law but the spirit as well, while encouraging more engagement and collaboration between the Animal Care and Use Program and the research community.
- UAC revised a disaster and contingency plan that meets USDA's new requirements.
- UAC has implemented species specific training for USDA species.

Since the last review, the following changes have occurred in the institution's program for animal care and use (PHS Policy IV.A.1.a.-i.):

The Spring 2022 Semi Annual Review Meeting Minutes (*attachment 1*) detail the IACUC's review of the Animal Care and Use Program. The meeting minutes were approved by the IACUC on 6/13/22. Each aspect of the Program is summarized below.

The following IACUC programmatic changes were implemented during the review period (November 2021 – April 2022):

1. University Animal Care (UAC) revised the existing emergency plan that meets new USDA requirements, for all applicable animal facilities.
2. The Attending Veterinarian (AV) delegated veterinary authority for [REDACTED] and CVM to DVMs within each program to allow for standard veterinary care.
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The MOU Summary document (*attachment 2*) lists animal research performed with University funds at external institutions covered by a Memorandum of Understanding. No reports of non-compliance were received over the past six months.



Description of the Nature and Extent of the Institution's Adherence to the PHS Policy, the *Guide*, and the AWA

Departures from the PHS Policy, the <i>Guide</i> , and the AWA.	
<input type="checkbox"/>	There were no departures during this reporting period.
<input checked="" type="checkbox"/>	<p>The IACUC reviewed the Departures and Exceptions Checklist, which lists both existing and new departures to the <i>Guide</i>. No departures were approved for either the PHS Policy or AWAR. Of note:</p> <p>Must:</p> <ul style="list-style-type: none">• 3 continuing protocols and 1 new protocol with departure from requirement for space for animals to turn around and/or rest away from urine and feces (<i>Guide</i>, p. 56) <p>Should:</p> <ul style="list-style-type: none">• 8 continuing protocols without acclimation to restraint (3 species known to acclimate well, 5 for scientific reasons). (<i>Guide</i>, p. 29)• 7 new, 16 renewal, and 165 continuing protocols for a total of 188 protocols with approved non-pharmaceutical grade compounds. (<i>Guide</i>, p. 31)• 7 continuing protocols with approval for use of expired materials. No anesthesia, analgesia, or euthanasia agents expired. (OLAW FAQ F.5, USDA APHIS Animal Care Policy #3)• 1 new and 9 continuing protocols for a total of 10 protocols using temperature and humidity studies and exception for humidity due to environmental factors. (<i>Guide</i>, p. 43)• 6 continuing and 1 renewal protocols using hypoxia; 1 continuing protocol with in-cage cigarette smoke exposure; 1 continuing protocol with variable ventilation; 1 continuing protocol with increased air flow for a total of 10 protocols (<i>Guide</i>, p. 45).• 4 continuing protocols with altered light cycle. (<i>Guide</i>, p. 47)• 1 continuing protocol with an exception to requirements for noise and vibration. (<i>Guide</i>, p. 49)• 11 continuing protocols, 1 renewal protocol, and 1 new protocol without bedding/enrichment and with an exception to keep animals dry, for post-surgical care, research necessity, and/or metabolic caging for a total of 13 protocols (<i>Guide</i>, p. 52, pp. 68-69)• 2 continuing protocols with approved departures from ability to escape or avoid aggression. (<i>Guide</i>, p. 55)• 2 continuing protocols for a total of 2 with ag animals housed singly (<i>Guide</i>, p. 60)• 12 continuing protocols without standard or additional enrichment for singly housed animals (<i>Guide</i> p. 64).• 1 renewal and 10 continuing protocols for a total of 11 with a departure from providing <i>ad libitum</i> water (<i>Guide</i> p. 67-68).• 3 renewal and 9 continuing protocols for a total of 12 with reduced cage & bedding change frequency (<i>Guide</i>, pp. 70-71)• All satellite housing is evaluated for scientific necessity. 7 continuing protocols with in-lab housing (<i>Guide</i>, p. 134)

Deficiencies in the Institution's Animal Care and Use Program

Animal Care and Use Program Review Date: May 5, 2022	
<input checked="" type="checkbox"/>	There were no deficiencies in the program during this reporting period.
<input type="checkbox"/>	The Semi-annual Program Review Checklist identifies programmatic deficiencies for the IACUC and UAC.

Deficiencies in the Institution's Animal Facility

Animal Facility Inspection Dates: January 31 – February 11, 2022 (UAC locations); April 4 – May 5, 2021 (PI peripheral laboratories)	
<input type="checkbox"/>	There were no deficiencies in the animal facility during this reporting period.
<input checked="" type="checkbox"/>	<p>The IACUC Semi-Annual Inspection Documents outline the 4 UAC and farm facilities inspected in Jan/Feb 2022: [REDACTED] and 150 unique peripheral PI lab or farm locations inspected in April - May 2022 located across campus.</p> <p>The types of findings are typical of previous inspections and generally represent expired items and missing or old signage.</p> <p>Two documents (<i>Attachments 3 and 4</i>) outline the results for the Winter and Spring inspections, and classified by the IACUC as Significant (2 findings in spring), Minor/SFI (16 in winter, 49 in spring), and No Findings (233 in winter, 87 in spring)</p> <p>Plans of action and dates are in place for any outstanding findings.</p>

Minority Views

<input checked="" type="checkbox"/>	No minority views were submitted or expressed.
<input type="checkbox"/>	The following minority view was expressed:

Status of AAALAC Accreditation

Continuing full AAALAC accreditation was received on March 4, 2020.

IACUC Semi-Annual Meeting

Minutes

8:30 am, Thursday May 5, 2022
Online via Zoom

Voting Members Present: Chair; M-1; NA-2; NS-1; S-2; S-3; S-6; S-7; S-8; S-9; V-1; V-2; V-3

Alternate Members Present: M-A-2; S-A-3; S-A-6; V-A-3

Voting Members Absent: NA-1; S-1; S-4; S-5

Visitors Present: A-1; Research Quality Assurance Officer; Assistant VP, Regulatory Affairs/Safety; Operations Manager, RLSS; IACUC Specialist 1; IACUC Specialist 2

The meeting was brought to order at 8:34 am and quorum confirmed with 13 of 17 members present.

Welcome and Introductions

1. The committee was thanked for their continued support to the research community and to the IACUC program

Announcements

1. Date of the next IACUC Monthly meeting was announced.
2. Date of the next IACUC Semi-Annual Meeting was announced.
3. There have been no changes to membership in the last 6 months.
4. Instructions for voting –
 - a. Voting will be virtual using Zoom via polls on screen.
 - b. Dissenting opinions can be emailed to AD, will be treated confidentially
5. TB tests – reminder. Of Note:
 - a) The committee requires some members to have TB tests annually to inspect primate locations.
 - b) TB tests are available to all members and available through Occupational Health Services.

IACUC, UAC Management Team and Occupational Health

1. **20-617*** -
 - a. Protocol was brought to the committee for FCR. Of note:
 - I. Veterinary staff had concerns regarding a 50% listed failure rate for behavioral experiments. Veterinarians requested further justification for animal increase and failure rate.
 - II. PI created a flowchart that explains the methodology in depth. The PI eliminated any failure rate for behavioral procedures and explained that the intention was to use bats that did not fit into a certain testing group would be used in a separate aim; essentially ensuring that all bats listed on the protocol are usable. PI, in addition, is implementing a surgical training program where students will practice neural surgery on rodent cadavers, then in terminal mice procedures, and lastly in bats for the experiment reducing the surgical failure rate dramatically. PI is working with veterinary staff for all surgical procedures and will adjust if needed.
 - b. **The IACUC requires modifications to secure approval:**
 - I. Clarify language regarding timeline of bats and how they will be used in different aims, depending on their adaptation to captivity and training
 - II. Final review by DMR (S-8)

2. **Non-Compliance/incidence reports**

a. The IACUC discussed new potential non-compliance. Of note:

I. **13-479:**

- i. PI was discovered not using appropriate ABSL2 procedures or animal housing for H1N1 influenza virus or working in a biological safety cabinet which as required for the ABSL2 work.
- ii. PI has stopped activity with H1N1, pending completion of requirements set by IBC
- iii. **The IACUC determined the following:**
 - 1) PI is to follow all recommendations for proper ABSL2 procedures, as indicated by UAC and IBC/RLSS
 - i. IBC requires entire lab, including PI, to retake biosafety level 1 and 2 trainings before anyone in the lab is allowed to work with H1N1 virus. This includes any animal or non-animal work.
 - 2) UAC will deliver additional training as a requirement for access to ABSL2 housing and spaces.
 - 3) A PAM visit will be scheduled, which will include training records to ensure all current and subsequent new staff are up to date on all training requirements.
- iv. Incident meets the threshold of non-compliance and is reportable to the IO and department chair

II. **16-209:**

- i. During a semi-annual inspection of [REDACTED] room [REDACTED], live animals were found unattended in a chemical hood. One of the animals was reported as euthanized ~3 days prior. In addition to the found animals, the lab space contained several expired agents that were unresolved from the last inspection.
- ii. The committee discussed the implementation of additional IACUC oversight including a PAM visit, implementing stronger action with repeat findings, as well as giving the veterinary staff key card access to the CORE imaging location, and a daily checklist to check for animals, expired items, etc.
- iii. The committee would like to notify all PI's using the facility of any future findings which would inform them of the current care and standard carried out by the CORE.
- iv. **The IACUC determined the following:**
 - 1) All protocol staff must retake all basic facility and CITI training relevant to protocol 16-209. This training is to be **completed within 7 days of this notice**. The required retraining is:
 - i. Working with the IACUC: Investigators, Staff and Students
 - ii. Working with Mice in Research
 - iii. Working with Rats in Research
 - iv. Reducing Pain and Distress in Laboratory Mice and Rats
 - v. Aseptic Surgery
 - 2) Provide all animal use SOPs in place for the MRI and PET/MRI core protocol, **within 30 days of this notice**.
 - i. This would include, but is not limited to:
 1. emergency procedures, non-surgical anesthesia protocols, euthanasia methods and procedures, fasting methods, routes of administration in use, husbandry procedures, and a comprehensive checklist to ensure that the welfare of all animals is ensured at all times while under the care of the core group.

- 3) If needed, the protocol should also be amended to make any corrections to the methods described.
- 4) All veterinary direction must be followed at all times. Future occurrences of failing to follow UAC direction will result in further IACUC action.
- 5) The IACUC findings of noncompliance related to the core facility must be relayed to current users of the MRI and PET/MRI core, along with sharing all SOPs. This notice must be reviewed by the Animal Welfare Program (AWP) prior to distribution.
- 6) A comprehensive Post-Approval Monitoring (PAM) visit will be scheduled to assist in identifying and correcting any issues, concerns, and ongoing challenges. This visit may include AWP, IACUC, veterinary, and RII Quality Assurance (QA) members, and a formal visit may be preceded or followed by additional visits that may be announced or unannounced.
- 7) UAC veterinarians and identified staff are to be provided “key” access to the facility.
- v. Incident meets the threshold of non-compliance and will be reported to the IO, Department Head, and TBIR management.

6. Review of UAC program

- a. The AV provided a review of the animal care program. Of note:
 - I. Centralized facility updates:
 - i. [REDACTED] HVAC operation has been completed after 18 months. Currently in the process of moving animals back into the empty spaces located in [REDACTED].
 - ii. Replaced a large section of [REDACTED] flooring.
 - II. Announced rate increase.
- b. AV designated veterinary authority for [REDACTED] and CVM to DVMs within each program to allow for standard veterinary care.
- c. Revised emergency plan.
 - I. AWA was modified in January with new requirements including but not limited to identifying emergency situations that are local, aligning specific task required to respond to an emergency, identifying the chain of command, and recovery.
 - II. New training requirements were implemented. Employees must have documented training within 30 days of their start.
 - III. UAC is responsible for all centralized facilities including PHX. Our non-centralized facilities [REDACTED], (satellite facilities) have individual emergency plans. USDA requirements must be implemented by July 1, 2022
 - IV. Plan is reviewed annually.
- d. COOP: required by the University to have a continuity of operations plan. In this we further outline our succession plan.
 - I. Both documents go to UAPD as part of the centralized emergency response.

7. Occupational health/animal hazards update

- a. The Occupational Health Manager/ RLSS Operations Manager provided an update of the Occupational Health program including the Animal Hazards program. Of note:
- b. Statistics from the Occupational Health program
 - I. Office has been performing increased recalls.
 - II. Increase in declinations.
- c. Statistics for the AHP program

- I. Total active participants have increased.

Break

A. IACUC Executive Session

1. Approve minutes

- a) The April 2022 meeting minutes were reviewed.
 - **The IACUC approved as written.**

2. Review of IACUC Program statistics

- a. The IACUC program statistics were presented. Of Note:
 - I. Total count of personnel and PI's have decreased
 - II. Total count of protocols has increased.
 - III. Submissions YTD were 171 and remain on an upward trend.
 - IV. No change in animal census.

3. Review of the program checklist

- a. The IACUC Program checklist was presented and reviewed. Of note:
 - I. Training concerns from last year were addressed and resolved.
 - II. No deficiencies found
- b. **The IACUC approved the program checklist as written.**

4. Review of Departures checklist

- a. The Departures and Expectations checklist was reviewed. Of note:
 - I. Reports are working and information should be accurate.
 - II. Any departures marked "New" are due to new protocols, not new to the program.
 - III. Number of details included in the comments was discussed and some updates made to the document during discussion.
- b. **The IACUC approved the review of departure checklist as written.**

5. IACUC semi-annual inspections with determination of plan of action

- a. Inspection metrics and semi-annual inspections were reviewed with follow up and determination and review of plans of action were discussed. Findings were verified as minor or significant. Of note:
 - I. Inspection metrics
 - i. Currently unavailable due to system malfunction. A report will be provided in June.
 - II. Winter 2021 – UAC locations
 - i. No findings were determined to be significant
 - ii. 240 total locations inspected
 - iii. 223 locations with no findings
 - iv. No locations with unresolved findings
 - v. 17 locations with resolved findings: Minor and suggestion for improvement
 - a. Reviewed and determined that actions already taken are sufficient
 - III. Spring 2021 – PI locations
 - i. A few outstanding locations – can determine severity and course of action in June
 - ii. 2 findings were determined to be significant
 - 1) 16-161: Expired Similac food (for pups). Date of expiration was April 1st, 2021. Was discarded during inspection. Similac was not on the protocol. Hypothermia of the pups is induced by placing pups in a fridge. This procedure is not an approved procedure and is not listed on the protocol.

2) 16-209: Several PI's using these rooms are not listed as responsible parties in our paperwork. Expired materials such as heparinized saline, saline, and contrast agent. Isoflurane scavenging canister not UTD. Inspectors found a cage with 2 animals (rats) on the chemical fume hood, one of the animals presented with a large wound on its back. The veterinarian present during the inspections reached out the vet services, upon record review they confirmed that the animal was supposed to have been euthanized 2 days prior by the lab contact. Vet services took over the case, and immediately euthanized the wounded rat and communicated to the Lab contact and PI of the situation and its detection during the IACUC inspection of the premises.

- iii. 52 locations with unresolved findings
- iv. All have been notified, waiting for response
- v. 11 locations with resolved findings: Minor and suggestion for improvement
- vi. 86 locations with no findings

Break

6. Review of IACUC programmatic changes made in the past six months

- a. University Animal Care revised the emergency plan to meet USDA requirements for all applicable facilities.
- b. AV designated veterinary authority for [REDACTED] and CVM to DVMs within each program to allow for standard veterinary care.
- c. The Animal Care and Use Program revised all satellite locations to have specific, individual disaster plans in place in addition to the programmatic disaster plan.

7. Review of MOU activity reports

- a. No adverse events reported from other institutions

8. Summary of incident, non-compliance, and adverse event reporting since last programmatic review

- a. 5 incidents/non-compliance
- b. 5 adverse events
- c. All events have been discussed and plans of action approved previously at convened IACUC meetings.

9. Programmatic report to the IO

- a. Continue to develop and implement lab training including species specific training for all USDA users.
- b. Discuss animal rights organizations increased activity and resulting safety concerns.
 - i. Increase of FOIA requests
- c. AWP is still in need of a Director.
- d. UAC revised a disaster and contingency plan

10. Final packet to be approved at June meeting

The meeting was adjourned at 11:44 am and quorum was maintained for the duration.

*Denotes a USDA species

Minutes complied by IACUC Specialist and distributed by IACUC Assistant Director.

This document is confidential and intended solely for the use of the individual or entity to whom it was addressed. If it is necessary to disseminate any of this information for official purposes, the non-essential information should be redacted.

Spring 2022

No reports of non-compliance or adverse events submitted by outside institutions

Active UA Memoranda of Understanding (MOU)

MOU #	UA PI	External Institution
2021-009-M		Texas Tech University Health Sciences Center
2020-002-M		Univeristy of Minnesota
2020-004-M		University of Nevada - Reno
2020-005-M		Johns Hopkins University
2020-007-M		Cincinnati Childrens Hospital
2020-009-M		Mayo Clinic - Jacksonville
2020-011-M		Joslin Diabetes Center
2021-001-M		University of South Florida
2021-002-M		Midwestern University
2021-003-M		Cedars-Sinai
2021-004-M		University of Miami (Animal Care)
2021-005-M		Emory University
2021-006-M		Johns Hopkins University
2021-007-M		UC Davis
2022-001-M		SUNY Stonybrook
2022-002-M, 2022-003-M		National Jewish Health

Active Non-UA MOUs

Protocol #	UA PI	External Institution
07-029		University of Arkansas
14-554		Wayne State University
16-170		Duke
[any]		SAVAMC
18-440		University of Michigan
06-036		University of Chicago
12-391		University of Pennsylvania
20-638		University of Miami
17-360		Midwest University



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