



DEPARTMENT OF THE ARMY
HEADQUARTERS, U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
810 SCHREIDER STREET
FORT DETRICK, MARYLAND 21702-5000

October 8, 2019

(b) (6)

Vice President for Research, Temple University

(b) (6)

Philadelphia, PA 19122

Dear (b) (6)

(b) (6) Director, and (b) (6) Manager, Animal Care and Use Review Office, Office of Research Protections, U.S. Army Medical Research and Development Command, accompanied by (b) (6) Laboratory Animal Medicine resident, conducted a site visit to the Temple University on September 17, 2019, to evaluate the animal care and use program and the animal care facilities. Participating individuals and results of the site visit are outlined in the enclosed checklist. Suggestions for improvement are offered in the absence of regulatory or guideline standards. These "best practices" are methods the staff observed to work well within other programs/facilities and are offered for the institute's consideration.

This AAALAC International-Accredited Animal Care and Use Program is compliant with federal Animal Welfare Regulations and the recommendations of the Guide for the Care and Use of Laboratory Animals (Institute for Laboratory Animal Research). The staff were professional and knowledgeable. The strong collegial culture at the institute was impressive.

The Animal Care and Use Review Office recommends continued funding of the supported animal research to appropriate Department of Defense agencies.

The point of contact for this action is the undersigned at (b) (6) or (b) (6)

Sincerely,

(b) (6)

Director, Animal Care and
Use Review Office

Enclosure

CC (w/ encl):

(b) (6) Protocol PI
(b) (6) IACUC Chair
(b) (6) IACUC Assistant Director
(b) (6) Attending Veterinarian
(b) (6) Contract Officer's Representative



COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST

Site/Visit Type:	Site Visit	Site Visited:	Temple University
Date(s) Of Visit:	17 Sep 2019	Award and Protocol #:	(b) (4)
Award PI Name:	(b) (6)	Awarded Organization:	Temple University
Funding Agency:	USAARL	Species Approved:	Sheep
Protocol PI Name:	(b) (6)	Site Visitors:	(b) (6)
Protocol Title:	(b) (4)		

I. Names and titles of personnel present at in- and out-brief:

NAME	TITLE OR DEPARTMENT
(b) (6)	Protocol PI
(b) (6)	IACUC Chair
(b) (6)	Acting Attending Veterinarian
(b) (6)	IACUC Assistant Director
(b) (6)	Operations Manager

II. IACUC Membership and Function:

	A	MD	SD	N/A
a. Appropriate constitution (at least 5 required members, or 3 required members if not PHS Assured)	X			
b. Non-affiliated members (NAM) attend meetings regularly	X			
c. Member appointments available and current	X			
d. IACUC member training program in place	X			
e. Appropriate documentation of IACUC training for all members to include alternates		X		
f. Mechanism in place for reporting welfare concerns	X			
g. IACUC function document (SOP/Policy/Instruction)				X

¹ A-acceptable

MD- minor deficiencies

SD- significant deficiencies



COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST

h. Instructions for reporting concerns prominently displayed throughout the facility	X*			
i. Reported concerns were well investigated by the IACUC	X			
n. Adverse events, violations, and animal welfare concerns reported to COO and documented in file				X
j. If part-time AV, written program of veterinary care including regularly scheduled visits to the facility				X

Comments:

e. While generally compliant with institutional requirements, there were several members who have not completed training that has been started. The IACUC should review training transcripts to ensure completion of required modules.

h. Site visitors did not observe animal welfare reporting signs within the vivarium but were assured during the exit brief that such signs are posted throughout the facility. ACURO recommends posting these signs in (b) (6) laboratory space since animals are held there for an extended period of time during experimentation. There was much discussion on this issue; this is not a regulatory requirement but rather a recommended suggestion for improvement.

III: IACUC Minutes and Protocol Review:

	A	MD	SD	N/A
a. Attendance records maintained either in minutes or elsewhere	X			
b. Quorum present at each meeting	X			
c. Minutes demonstrate IACUC business other than protocol review	X			
d. Documentation in minutes or elsewhere of protocol review details	X			
e. Dissenting opinions included and explained				X
f. IACUC documents and protocol records maintained for at least 3 years	X			
g. Protocols contain sufficient detail	X			
h. Annual protocol reviews conducted and documented	X			
i. Scientific justification for exceptions to AWARs and the Guide present in applicable protocols	X			
j. COO approval documents included in protocol files	X			
k. Appropriate keywords used for databases searched	X			
Dates of minutes reviewed: December 2017, April 2019, June 2019, July 2019, August 2019				
Comments: Minutes are well written and inclusive of details to demonstrate conduct of IACUC business.				

¹ A-acceptable

MD- minor deficiencies

SD- significant deficiencies



COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST

IV: Semi-Annual Facility Inspection and Program Review (FIPR):

	A	MD	SD	N/A
a. FIPRs conducted and reports generated at least every six months		X		
b. At least two members participated in every area of the FIPR		X		
c. Non-affiliated member participation	No way to determine			
d. Deficiencies appropriately classified as minor or significant	X			
e. Report includes a reasonable and specific plan for correction of each deficiency with correction deadlines	X			
f. Individual responsible for correction of each deficiency identified	X			
g. Report identifies all locations visited during the facility inspection and areas of the program reviewed	X			
h. Departures from the provisions of the AWARs and the Guide are identified and justified	X			
i. Minority opinions are addressed	X			
j. Reports are signed by majority of IACUC members	X			
k. Documentation indicating reports are forwarded to IO	X			
Dates of FIPR reports reviewed: Fall 2017, Spring 2018, Fall 2018, Spring 2019				
Comments: a. The Fall 2018 report wasn't completed within 6 months of the Spring 2018 report. The Animal Welfare Regulations require that reports be updated no less than every 6 months. This was the only report not submitted in a timely manner and if it was a result of a unique situation, recommend attaching a memorandum to the report describing the circumstances. b-c. None of the reports indicated which members participated in either the program review or facility inspection. There is no regulatory requirement to identify individuals but since participation in all aspects of the semi-annual is a requirement of the Animal Welfare Regulations, there should be some indication that this requirement is being met. e. The correction plans presented were thorough and demonstrated escalating attention by the IACUC in areas where systemic deficiencies exist. The format is clear and sufficient information was provided to allow both an Institutional Official and site visitors to evaluate the appropriate function of the Committee in conduct of facility inspections. General: In reviewing all of the reports provided, no single programmatic deficiency was identified. In a program of this size, the lack of identified areas for improvement in a program of this size could indicate a lack of depth of program review. The IACUC				



COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST

should evaluate how program review is conducted, including a review of the Guide requirements for special consideration by the Committee, to confirm that this process is conducted appropriately.

V: General:

	A	MD	SD	N/A
a. Up-to-date listing of all SOPs, including most recent review date in accordance with SOP	X			
b. Comprehensive Disaster Plan in place that covers animal disposition and prioritization?	X			
c. Disaster Plan identifies essential personnel	X			
d. Disaster Plan part of the institution's overall emergency response program	X*			
e. Comprehensive occupational health and safety (OHSP) plan in place	X			
f. All staff members, to include contractors, evaluated as part of the OHSP. If not, procedures are in place to ensure individuals not included in the OHSP have alternative means of evaluation	X			
g. Acceptable Psychological Well-Being Plan for NHPs in place, if applicable				X
h. Acceptable Exercise Plan for Dogs in place, if applicable				X
i. Environmental Enrichment Plan covers for all species	X			
j. Mechanism in place to assure all protocol personnel have been trained to perform their role	X			
k. Training records match the training requirements of the institution and IACUC	X			

Comments:

d. The disaster plan provided had no indication that local first responders or law enforcement had visibility of the program in order to mitigate miscommunication or access in the event of an emergency. During the exit brief, site visitors were informed that a larger, more comprehensive emergency response plan exists for the university that was not provided for review. Reportedly, this larger plan does describe interaction with local public safety personnel.

f. For the facility walk-through, N-95s are to be worn by personnel working with sheep. Though the occupational health documentation reviewed by the site visitors did not document respirator fit testing requirements, personnel on site assured the site visitors that this is reviewed initially and annually as part of the occupational health program.

V. FUNDED ANIMAL WORK:¹ A-acceptable

MD- minor deficiencies

SD- significant deficiencies



COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST

EXTRAMURAL SITES ONLY	A	MD	SD	N/A
a. Observed animal procedures are being performed as reviewed and approved by ACURO				X
b. All personnel performing animal procedures approved in the IACUC protocol				X
c. All changes to the protocol been reviewed and approved by the local IACUC		X		
d. All changes to the protocol been approved by ACURO		X		
Comments: No experimental procedures were observed during the visit. c-d. Medical records reviewed demonstrated experimental anesthetic events lasting much longer than those described in the protocol or ACURO appendix. While animal observations were almost constant during the experiment and no animal welfare issues existed for animals enrolled in the protocol, the PI was advised that this was a protocol violation that needed to be corrected immediately by IACUC review and approval of an amendment to the protocol, which needs to be forwarded on to ACURO for review and approval as soon as possible. The PI assured site visitors that this minor noncompliance would be corrected immediately.				

VETERINARIAN REVIEW:

I. PHYSICAL ENVIRONMENT	A	MD	SD	N/A
a. Microenvironment and Macroenvironment	X			
b. Housing	X			
c. Space Recommendations	X			
d. Temperature and Humidity	X			
e. Ventilation	X			
f. Illumination	X			
g. Noise/Vibration	X			
Comments: The animal facility, hallways, and surrounding areas were clean and well-stocked with supplies. The PI maintains registration with the DEA and individually controls drugs within the lab.				

II. BEHAVIORAL MANAGEMENT	A	MD	SD	N/A
a. Structural Environment	X			
b. Social Environment	X			
Comments: Though efforts are made to socially-house all animals, during this site visit only one sheep was in house awaiting procedures. This sheep was provided extra physical space and additional environmental enrichment. The social needs of the animals are considered and attended to as sheep are paired (b) (4) and, when possible, paired for transportation in the facility.				

III. HUSBANDRY	A	MD	SD	N/A
----------------	---	----	----	-----

¹ A-acceptable

MD- minor deficiencies

SD- significant deficiencies



COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST

a. Food	X			
b. Water	X			
c. Bedding				X
d. Sanitation	X			
e. Waste Disposal	X			
f. Pest Control	X			
g. Emergency, Holiday, and Weekend Care	X			
Comments: Signage throughout the facility clearly displays after-hours and emergency phone numbers to reach appropriate personnel. Animals on this study are not housed using bedding.				

IV. POPULATION MANAGEMENT	A	MD	SD	N/A
a. Identification and Records	X			
b. Genetics and nomenclature				X
Comments:				

V. ANIMAL PROCUREMENT AND TRANSPORTATION	A	MD	SD	N/A
a. Quarantine, Stabilization, and Separation	X			
b. Surveillance, Diagnosis, Treatment, and Control of Disease	X			
Comments: Animals on this study are pre-screened for Q fever before entering the vivarium. These records were available for review. (b) (4)				
(b) (4)				

VI. VETERINARY MEDICAL CARE	A	MD	SD	N/A
a. Preventive Medicine	X			
b. Surgery				X
c. Facilities for Aseptic Surgery				X
d. Pain, Analgesia, and Anesthesia	X			
e. Euthanasia	X			
Comments: Surgery was not performed on the animals that had undergone procedures for this study. (b) (4) Pain scoring sheets are available in the animal rooms with clear instructions regarding course of action to take if an animal exhibits any signs of pain. (b) (4)				
(b) (4)				

VII. FUNCTIONAL AREAS	A	MD	SD	N/A
a. Corridors	X			
b. Animal Room Doors	X			



COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST

c. Exterior Windows				X
d. Floors	X			
e. Drainage	X			
f. Walls	X			
g. Ceilings	X			
h. Heating, Ventilation, and Air Conditioning (HVAC)	X			
i. Power and Lighting	X			
j. Storage Areas	X			
k. Noise Control	X			
l. Facilities for Sanitizing Materials	X			
Comments: As previously noted, the animal facility was clean and well-organized as was the investigator's laboratory/animal use area. Though not a deficiency, the limitations of the drainage system require an additional step of feces removal rather than utilizing the drain for feces disposal.				