



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

June 5, 2019

(b) (6)

Vice President for Research Operations and Student Affairs  
Oregon Health and Science University

(b) (6)

Portland, OR 97239

Dear (b) (6)

(b) (6) Chief, Animal Protections, Office of the Surgeon General (HQDA), and (b) (6) Manager, Animal Care and Use Review Office, Office of Research Protections, U.S. Army Medical Research and Development Command, conducted a site visit to the Oregon Health and Science University on 22 May 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 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) Award and Protocol PI  
(b) (6) Science Officer  
(b) (6) Contract Specialist  
(b) (6) IACUC Point of Contact  
(b) (6) Attending Veterinarian



## COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST

Site/Visit Type:	Site Visit	Site Visited:	Oregon Health and Science University
Date(s) Of Visit:	22 May 2019	Award and Protocol #:	(b) (4)
Award PI Name:	(b) (6)	Awarded Organization:	Oregon Health and Science University
Funding Agency:	CDMRP	Species Approved:	Swine
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)	PI
	Laboratory Manager
	Attending Veterinarian
	IACUC Representative

## 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			
h. Instructions for reporting concerns prominently displayed throughout the facility	X			
i. Reported concerns were well investigated by the IACUC	X			

<sup>1</sup> A-acceptable

MD- minor deficiencies

SD- significant deficiencies





## COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST

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
<b>Comments:</b> e. The institution was unable to provide any documentation of initial training required for all IACUC members. Ongoing training is documented in meeting minutes but the institution must develop a mechanism to capture completion of all required training in accordance with institutional policy. f. While there is no specific policy developed by the IACUC for the purposes of reporting and investigating animal welfare concerns, the Assurance describes the program well. Recommend copying that information into a brief institutional policy to demonstrate appropriate attention to this important area. h. While instructions for reporting animal welfare concerns were clearly visible throughout the vivarium, no signs were posted in the lab area where students are actually observing (b) (4). Signs should be posted in this area as well and procedures for reporting briefed prior to the live tissue portion of the course. Also consider whether this area should be compliant with the IACUC policy on animal use outside the vivarium that indicates such areas should be designated by signage.				

**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: Sept 2017, Feb 2019, Mar 2019				
<b>Comments:</b> Minutes are very well organized and amply demonstrate the Committee's engagement in the program, including documentation of continuing education.				

<sup>1</sup> 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	X			
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: Aug 2017, Feb 2018, Aug 2018, Feb 2019				
<b>Comments:</b> b. While the reports clearly indicate the number of IACUC members participating in facility inspections, there is no such indication for the program review. The Animal Welfare Regulations do not differentiate between program review and facility inspection for the 2 member requirement. Recommend inclusion of a statement in the report that at least 2 members participated in the conduct of program review. e. The (b) (4) included some deficiencies noted with 'corrected' or 'reported to facilities' rather than a deadline for correction. While it's completely acceptable to track progress, the IACUC determined date for correction needs to be present to demonstrate that the correction is made prior to that deadline. This deficiency was only noted on the most recent report. General: The template utilized by the IACUC for the correction plan is among the best seen by the site visitors. It enables the Institutional Official to see at a glance, any issues that may be systemic to the institution as well as those areas that have repeated noncompliance.				

## V: General:

	A	MD	SD	N/A

<sup>1</sup> A-acceptable

MD- minor deficiencies

SD- significant deficiencies





## COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST

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		
<b>Comments:</b> c. ACURO was impressed by the (b) (4) outlined in the emergency response plan. Allowing investigators to identify highly valuable animals before an emergency occurs can ensure appropriate prioritization and eliminate confusion and potentially disastrous outcomes for researchers. j-k: No documentation of training completed by staff was provided to the site visitors. In addition, the IACUC representative was unable to describe how the IACUC oversees the training program for individuals working with animals. During the exit brief, the PI indicated PIs are responsible for conducting training for their staffs and that an individual cannot be listed on the protocol without completing required training. This program should be documented and some mechanism for oversight by the IACUC developed.				

## V. FUNDED ANIMAL WORK:

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		

<sup>1</sup> A-acceptable

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## COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST

**Comments:** d. The institute must develop a mechanism to ensure submission of all lifecycle actions, include amendments and triennial reviews as described in the attached guidance, to ACURO for review and approval prior to implementation.

**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			
<b>Comments:</b> b. and c: see annotation below.				

II. BEHAVIORAL MANAGEMENT	A	MD	SD	N/A
a. Structural Environment	X			
b. Social Environment	X			
<b>Comments:</b> b. It's especially notable that the animals have open access to several enclosures so that they can determine whether to house themselves in a group or individually while maintaining sufficient floor space overall.				

III. HUSBANDRY	A	MD	SD	N/A
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			
<b>Comments:</b> a. The group-housed animals are fed individually, a good practice for pigs.				

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

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			





## COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST

**Comments:**

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			
<b>Comments:</b> The following were noted as positive practices done while the animals were either waiting for or (b) (4) b. Automated equipment ensures continuous monitoring of anesthetized animals and the staff ensures that an additional assessment is performed at regular intervals, every 15 minutes or less. d. Great care is taken to ensure proper anesthesia throughout the procedures and especially during the (b) (4)				

VII. FUNCTIONAL AREAS	A	MD	SD	N/A
a. Corridors	X			
b. Animal Room Doors	X			
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
<b>Comments:</b> l. the cagewash facility was not visited				