



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

14 March 2019

(b) (6)

Vice Provost for Research  
University of Miami  
Miami, FL 33136

(b) (6)

(b) (6) Chief of Animal Protections of the Veterinary Service Directorate, Deputy Chief of Staff for Public Health, Office of the Surgeon General and (b) (6) Executive Officer, Animal Care and Use Review Office, Office of Research Protections, U.S. Army Medical Research and Materiel Command, conducted a site visit to the University of Miami, School of Medicine, Miami, FL 6-7 February 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 strong collegial culture at the institute was impressive.

The Animal and 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)

(b) (6)

Director, Animal Care  
and Use Review Office

Enclosure  
cc (w/ encl):

(b) (6) Associate Director, Animal Protection Programs in the Office of the Under Secretary of Defense, Research, and Engineering

(b) (6) Chief, Animal Protections, Veterinary Service Directorate, Deputy Chief of Staff for Public Health, Office of the Surgeon General (HQDA)

(b) (6) Director of Compliance, University of Miami Office of Research

(b) (6) IACUC chair

(b) (6) Award Principal Investigator, University of Miami

(b) (6) Principal Investigator, University of Miami



ACDRO0000003

## COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST



Site/Visit Type:	Extramural	Site Visited:	University of Miami – Miller School of Medicine
Date(s) Of Visit:	6-7 February 2019	Award and Protocol #:	Award (b) (4) Protocol (b) (4)
Award PI Name:	(b) (6)	Awarded Organization:	University of Miami – Miller School of Medicine
Funding Agency:	CTT	Species Approved:	Pig ( <i>Sus scrofa domestica</i> )
Protocol PI Name:	(b) (6)	Site Visitors:	(b) (6)
Protocol Title:	Fast forward surgical team: Mass casualty drill		
<b>Human Medical Training Only</b>			
Course Taught: FFST: MASCAL	_12_ days of didactic training _2_ days of live animal procedures		
Service Component: <input checked="" type="checkbox"/> Conventional Army <input type="checkbox"/> Conventional Air Force <input type="checkbox"/> Conventional Navy/Marine Corps <input type="checkbox"/> Special Operations Command (SOCOM)			
(b) (4)	# of Students Trained: 24	# of Animals Used: 7	

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

NAME	TITLE OR DEPARTMENT
(b) (6)	IACUC Admin & Director, Compliance (In & outbrief)
(b) (6)	AV & Dir, Division of Veterinary Resources (DVR) (In & outbrief)
(b) (6)	Protocol PI & Professor of Surgery (In & outbrief)
(b) (6)	Proposal/Award PI, Dept. of Surgery (Inbrief)
(b) (6)	Trauma Surgeon, Army Trauma Training Detachment (ATTD) (In & outbrief)
(b) (6)	Protocol assistant to Dr Proctor, Dept of Surgery (In & outbrief)
(b) (6)	Supervisor, Veterinary Technicians, DVR (Outbrief)
(b) (6)	Employee health nurse (Outbrief)





## COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST

## 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			
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>INTRAMURAL SITES ONLY</b>				
k. IACUC has at least 1 regular and 1 alternate NAM				x
l. Documentation of approved waivers from COO for any IACUC meeting where a NAM isn't present				x
m. IACUC training records include the 8 hours of required training for all members and alternates				x
<b>Comments:</b> We commend the IACUC staff for their well-organized meticulous documentation of IACUC activities and the animal care and use program. This greatly facilitated efficient review of the program by the ACURO team.  <i>Section h.</i> The <i>Guide for the Care &amp; Use of Laboratory Animal</i> (pg 24) states that signage with instructions for reporting concerns related to animal welfare should be posted in prominent locations in facilities where animals are used. While signs were posted in the University of Miami vivarium, no signage was posted in the area where pigs were used for training. As a result, the students in the course have no access to the contact information provided on the signs for reporting concerns. The institution should ensure proper signage is posted that provides animal users information on reporting animal welfare concerns.				

## III: IACUC Minutes and Protocol Review:

	A	MD	SD	N/A

<sup>1</sup> A-acceptable

MD- minor deficiencies

SD- significant deficiencies



## COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST

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			
<b>INTRAMURAL SITES ONLY</b>				
l. Required database searches for duplication				X
m. Protocol coversheet contains all required signatures				X
n. Protocols written in current DoD standardized format				X
Dates of minutes reviewed: ACURO site visitors reviewed minutes from the two most recent IACUC meetings (4 Oct 2018 & 1 Nov 2018) and from the 2 meetings in which this protocol was discussed (2 Feb 2018 & 1 Mar 2018).				
<b>Comments:</b>				

**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			

<sup>1</sup> A-acceptable

MD- minor deficiencies

SD- significant deficiencies





## COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST

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: ACURO site visitors reviewed the 2 most recent reports of facility inspection (6 May 2018 & 7 Nov 2018) and program review (6 Mar 2018 & 6 Sep 2018).				
<b>Comments:</b> We commend the IACUC office for conducting semiannual facility inspections and program reviews that were thorough and very well documented, demonstrating a very professional, engaged, and highly proficient IACUC staff.				

**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			
<b>Comments:</b> We commend the institution for maintaining a disaster preparedness plan covering the animal facilities that stands out for being very thorough, well thought out, practical, and executable.				



## COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST

*Section f.* According to institutional IACUC policies (see section F2) personnel with animal contact are required to undergo a baseline health assessment. For the Fast forward surgical team: Mass casualty drill course, there is no provision for occupational health evaluation of students participating in the course. In consult with DVR and occupational health personnel, the institution should develop and implement appropriate procedures for occupational health evaluation of course participants.

**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			
<b>Comments:</b> Site visitors evaluated all areas related to care and use of pigs used in the Fast forward surgical team: Mass casualty drill. Site visitors also evaluated all areas related to care and use of (b) (4)				

**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> We commend the DVR staff for a vivarium that was very clean and well maintained and for a robust and well-executed program of enrichment for animals evaluated during the visit (swine, marmosets).				

II. BEHAVIORAL MANAGEMENT	A	MD	SD	N/A
a. Structural Environment	X			
b. Social Environment		X		
<b>Comments:</b> <i>Section b.</i> Institutional policies (b) (4) describe social housing as the default for social species and specify the use of cage identification to document reasons for animals being singly housed. One pig and multiple marmosets were single housed. However, no cage level identification addressing the reason for single housing was used. There was a lack of documentation in the animal medical records as to the reason for				





## COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST

single housing. Single housing was not addressed or explained in the corresponding animal use protocols. The institution should ensure that policies, procedures, and protocols address social housing of animals and are up-to-date, fully implemented, and adequately documented.

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			

**Comments:**

Section e. In accordance with the Guide for the Care & Use of Laboratory animals (pg 142) animal carcasses should be stored at 7degC or lower. Per University of Miami DVR (b) (4) all carcasses are stored in coolers or freezers. It was noted during the site visit that carcasses left over from the first night's exercise (ending ~10pm) are not held in a cooler or refrigerator as the SOP indicates. In consult with DVR and safety personnel, the institution should develop and implement appropriate procedures for storage of animal carcasses used in the course.

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:**

We commend the DVR staff for their efficient handling, transportation, and delivery of animals for use in the course. The staff were notably well prepared, proficient, and knowledgeable.

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			





## COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST

**Comments:**

*Section d.* Per institutional IACUC policies (see section J4), animal medical records should include anesthesia records. DVR staff appropriately maintains anesthesia and associated records until the time of hand-off to training personnel. The training staff maintain anesthesia records (including anesthetic depth assessment, controlled substances administration, etc.) for the remainder of the course. However, these records are not archived in the animal's medical record. We acknowledge that the PI and the IACUC have already recognized this issue and assured the ACURO site visitors that going forward, anesthesia monitoring records will be included in the animal medical record. The IACUC should follow up to confirm appropriate procedures for documentation of anesthesia monitoring.

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			

**Comments:**