



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

4 December 2019

(b) (6)

Institutional Official
Baylor University School of Medicine
One Baylor Plaza, (b) (6)
Houston, TX 77030

Dear (b) (6)

On behalf of Animal Care and Use Review Office, Office of Research Protections, U.S. Army Medical Research and Development Command, (b) (6) conducted a site visit to the Baylor College of Medicine in Houston, Texas on January 9 – 10, 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 that the staff observed to work well within other programs/facilities and are offered for the Administration's and the Institutional Animal Care and Use Committee'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 Animal Care and Use Review Office recommends continued funding of the supported animal research to appropriate Department of Defense agencies.

Note that in a recent review of records, we noted that this report had not been sent to your institution.

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) [REDACTED] Award Principal Investigator
(b) (6) [REDACTED] Protocol Principal Investigator
(b) (6) [REDACTED] IACUC Chair
(b) (6) [REDACTED] Attending Veterinarian
(b) (6) [REDACTED] Contract Officer's Representative
(b) (6) [REDACTED] Contract Specialist
(b) (6) [REDACTED] DARPA Representative



COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST



Site/Visit Type:	ACURO	Site Visited:	Baylor College of Medicine
Date(s) Of Visit:	10 January 2019	Award and Protocol #:	(b) (6)
Award PI Name:	(b) (6)	Awarded Organization:	Baylor College of Medicine
Funding Agency:	CDMRP, DARPA	Species Approved:	Canis lupus familiaris
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)	DOD Award Principal Investigator
(b) (6)	IACUC Protocol Principal Investigator
(b) (6)	IACUC Chair
(b) (6)	Associate Investigator
(b) (6)	Associate Investigator
(b) (6)	Attending Veterinarian
(b) (6)	IACUC Administrator

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			

¹ A-acceptable

MD- minor deficiencies

SD- significant deficiencies



COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST



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
Comments: Very robust IACUC with over 24 members and great support from the college and BEST PRACTICE: comprehensive training program (online CITI or AALAS Learning) with opportunities to attend SCAW, PRIMR and various other IACUC training venues. BEST PRACTICE: They have a mentor program for their new IACUC members. The mentors assist with protocol reviews and facility inspection and program review procedures. Occupational Medicine doctor attends all meetings and provides OHS update.				

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: 2/21/2018; 10/16/2018; 11/26/2018; and 12/13/2018				
Comments: Post Approval Monitoring program initiated in Nov 2017 and has been received very well.				

IV: Semi-Annual Facility Inspection and Program Review (FIPR):¹ A-acceptable

MD- minor deficiencies

SD- significant deficiencies



COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST



	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: 6/27/2017; 12/19/2017; 6/26/2018; 12/18/2018				
Comments: BEST PRACTICE: The Institutional Official meets with the Attending Veterinarian, Director of Comparative Medicine, Associate Dean of Research, resource management and veterinarians after each FIPR to review and prioritize the findings and recommendations.				

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			



COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST

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: Finding: CCM policies have no way to track when they are reviewed and if there are no changes. For example, (b) (4) but no annotation made to show that it was reviewed and no changes made. Recommend: Adding a location where the reviewer can sign and date when policy was reviewed and no changes needed to be made. BEST PRACTICE: Comprehensive training program for researchers and lab personnel. They have a Training Ambassador for each rodent surgery protocol, trained by veterinary staff, who then trains the surgery procedure and monitors everyone else on the protocol.

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
Comments: Currently no changes have been submitted to the protocol.				

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:				

II. BEHAVIORAL MANAGEMENT	A	MD	SD	N/A
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MD- minor deficiencies

SD- significant deficiencies



COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST

a. Structural Environment	X			
b. Social Environment	X			
Comments:				

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:				

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:				

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:				

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			



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COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST

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:				

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