



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

May 28, 2019

(b) (6)

Senior Vice President for Research
Massachusetts General Hospital

(b) (6)

Boston, MA 02114

Dear (b) (6)

(b) (6) Executive Officer, 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 Massachusetts General Hospital on 9 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)

(b) (6)

Director, Animal Care and
Use Review Office

Enclosure

CC (w.encl):

(b) (6) Principal Investigator
(b) (6) Animal Welfare Assurance Director
(b) (6) Attending Veterinarian
(b) (6) Contract Specialist
(b) (6) COR
(b) (6) Science Officer



COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST

Site/Visit Type:	Site Visit	Site Visited:	Massachusetts General Hospital
Date(s) Of Visit:	9 May 2019	Award and Protocol #:	(b) (4)
Award PI Name:	(b) (6)	Awarded Organization:	Massachusetts General Hospital
Funding Agency:	CDMRP	Species Approved:	Nonhuman Primates
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's representative
	Acting Attending Veterinarian
	Animal Welfare Assurance Director
	Clinical Veterinarian
	IACUC Manager
	Assistant Director of Operations
	Assistant Director of Operations
	IACUC Compliance Officer

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			

¹ A-acceptable

MD- minor deficiencies

SD- significant deficiencies



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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			
j. Adverse events, violations, and animal welfare concerns reported to COO and documented in file	X			
k. If part-time AV, written program of veterinary care including regularly scheduled visits to the facility				X
Comments: e. Recommend the institute consider making use of refresher training for IACUC members in CITI. Additionally, training policies should either exempt nonvoting members from the training requirements or they should be enrolled in the IACUC member training program.				

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			
Comments: none				

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			



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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: Spring 2017, Fall 2017, Spring 2018, Fall 2018				
<p>Comments:</p> <p>e. Reports of facility inspections were very thorough, revealing the significant effort and high level of engagement of the IACUC in facility improvement and oversight of animal care and use. However, the IACUC utilizes a system in which multiple deficiencies may be noted on a single entry. On the Spring 2017 report of the facility inspection and program review, one such entry did not contain a plan for correction of all the deficiencies noted in the entry. The institution must be sure to address each deficiency noted. In addition, each deficiency must have a defined schedule for correction, followed by a separate entry when the deficiency is rectified to demonstrate timely correction.</p> <p>e. Consistently recurring issues with particular areas such as expired drugs, uncertified equipment, repeat findings with dirty caging, and unlabeled compounds should precipitate institutional responses aimed at prevention and compliance rather than just repeatedly making corrections to a long term problem. Such responses should be captured in the reports to the IO.</p> <p>General recommendation: Recommend that repeat findings be identified to the IO for additional focus on consistently noncompliant PIs.</p>				

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			

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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: a. Policies that identify reporting requirements, such as the animal welfare concerns and amendment policies, should be updated to include DoD oversight offices among the reporting and submission requirements.				

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: none				

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:				

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a. The transport van used to transport animals between different research sites is typically sanitized every 6 months. On inspection, animal bedding was noted on the floor of the transport compartment of the vehicle. Per the Guide (pg 107), transportation should provide an appropriate level of biosecurity and minimize zoonotic risk. In order to minimize the risk of cross-contamination between animals and between animals and personnel that sometimes ride in the transport compartment, the institution should evaluate cleaning and sanitation practices of the transport vehicle and implement procedures to improve sanitation of the transportation compartment.

II. BEHAVIORAL MANAGEMENT	A	MD	SD	N/A
a. Structural Environment	X			
b. Social Environment	X			
Comments: None.				

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: a. Fruits and vegetables are fed to primates, including immunocompromised primates. However, there is no procedure for washing or sanitizing the fruits/vegetables. Recommend instituting procedures for washing/sanitizing fruits and vegetables fed to nonhuman primates in order to decrease risk of transmission of foodborne pathogens. d. Cage wash temperatures are verified using chemical indicator strips. However, there is no method in place for regular assessment of effectiveness of sanitation for items cleaned in the cage washer. The Guide (pg 73) recommends regular evaluation of sanitation effectiveness of equipment, including caging using appropriate methods (e.g., culture, ATP detection, artificial soil removal, etc.). The institution should develop and implement procedures for regular evaluation of effectiveness of cage wash sanitation. General comments: MGH staff were highly competent, knowledgeable, and clearly well trained, resulting in a well-run program and well cared for animals.				

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



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a. Animal medical records were very thorough and well organized, which greatly facilitates assessment of the comprehensive health history and tracking of treatments for each animal.

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: None.				

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: b. The surgical suites were well set up, modernized, and well maintained. The surgical support team was knowledgeable and offered an impressive array of surgical support capabilities.				

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: d. The floor of the lift ramp in the cage wash area had a significant amount of accumulated debris, increasing the risk of contamination of clean cages as they exit the cage washer. Per the Guide (pg 72), cage wash areas should be regularly cleaned and disinfected based on usage and risk of contamination. The institution should evaluate equipment and procedures for cleaning and maintenance of the cage wash area in order to decrease the risk of contaminating clean cages that will be used to house animals. h. ABSL 2 nonhuman primate housing rooms are maintained at negative pressure relative to the hallway, as recommended by the Guide (pg 139). However, there is no				



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current method for regular verification or documentation of room air pressure differentials. Pressure differentials are only verified up to once every 2 years when HVAC assessment is done. Additionally during the visit, the door to an NHP room was observed to have been propped open for an unknown period of time. We recommend evaluation of biosecurity policies and practices and development of procedures for maintenance and regular verification of appropriate pressure differentials in animal housing and other applicable areas.