



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

September 26, 2019

(b) (6)

Director of Research, St. Vincent's Hospital
Oversight Agency, Bionics Institute of Australia

(b) (6)

East Melbourne, Victoria 3002

Dear (b) (6)

(b) (6) Deputy Director and (b) (6) Animal Program Oversight Specialist, Animal Care and Use Review Office, Office of Research Protections, U.S. Army Medical Research and Development Command, conducted a site visit to the Bionics Institute, Melbourne on 30 August 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. When relevant, suggestions for improvement are offered in the absence of regulatory or guideline standards. These "best practices" are methods our staff have observed to work well within other programs/facilities and are offered for the institute's consideration.

This Program was compliant with applicable Department of Defense policies. 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)

(b) (6)

Director, Animal Care and
Use Review Office

Enclosure

CC (w/ encl):

(b) (6) Bionics Institute
(b) (6) Bionics Institute
(b) (6) Congressionally Directed Medical Research Programs
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COMPONENT OVERSIGHT OFFICE (COO) VISIT CHECKLIST

Site/Visit Type:	International Extramural	Site Visited:	Bionics Institute of Melbourne
Date(s) Of Visit:	30 August 2019	Award and Protocol #:	(b) (4)
Award PI Name:	(b) (6)	Awarded Organization:	The Bionics Institute of Melbourne
Funding Agency:	CDMRP	Species Approved:	Feline
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)	Chief Operating Officer
	Award and Protocol Principal Investigator
	Senior Research Assistant
	Attending Veterinarian
	Animal Ethics Committee Secretary

*= out brief only, ^= in and out brief

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

Obtained by Rise for Animals. Uploaded 08/12/2020

Retrieved from Animal Research Laboratory Overview (ARLO)



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:				

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: 29 May 2018 (SVHM AEC), 15 May 2019 (SVHM AEC), 19 Jun 2019 (Bionics AEC), 17 July 2019 (Bionics AEC)				
Comments: General: 15 May 2019 minutes document transfer of program oversight from Bionics Institute of Melbourne to the St. Vincent's Hospital Melbourne Animal Ethics Committee (SVHM AEC). General: Minutes were well written and included many details of protocol review as well as other AEC business.				



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

	A	MD	SD	N/A
a. Inspections conducted and reports generated	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 inspection reports reviewed: 2 July 2019 (SVHM AEC), 26 February 2019 (Bionics AEC), 20 November 2018 (Bionics AEC), 15 October 2019 (Bionics AEC)				
Comments: b. Australian code of practice for the care and use of animals for scientific purposes, 8 th Edition, section 2.3.20 strongly recommends a C or D AEC member participate in inspections. Currently participation by C or D AEC members is sporadic. Recommend encouraging increased participation from C and D AEC members in facility inspections. (<i>best practices</i>)				

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. Australian code of practice for the care and use of animals for scientific purposes, 8 th Edition, section 2.2.35 states that reference SOPs must be reviewed at least every 3 years and if approval for the SOP lapses the SOP cannot be used. During the inspection expired SOPs were identified. The aforementioned SOPs must be updated and approved by the AEC before procedures described in the SOPs can be conducted on animals funded by this award.				

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: c. and d. ACURO has updated the guidance for submission of protocol changes. This guidance document was sent to the PI for reference.				

VETERINARIAN REVIEW:

I. PHYSICAL ENVIRONMENT	A	MD	SD	N/A
a. Microenvironment and Macroenvironment	X			
b. Housing	X			
c. Space Recommendations	X			

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d. Temperature and Humidity	X			
e. Ventilation	X			
f. Illumination	X			
g. Noise/Vibration	X			
Comments: Observed animals assigned on this protocol. Animals were well maintained and cared for.				

II. BEHAVIORAL MANAGEMENT	A	MD	SD	N/A
a. Structural Environment	X			
b. Social Environment	X			
Comments: Animals received comprehensive environmental enrichment. Animals demonstrated normal behavior.				

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			

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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			
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:				