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OMB APPROVED  
0579-0036  
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control  
No. 0180-DCA-AN

Fiscal Year 2018

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY  
(TYPE OR PRINT)

1. REGISTRATION NUMBER

14-R-0192 (Customer Number: 23918)

2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code)

57 Union Street  
Worcester, MA  
01608

Telephone: 508-459-7544

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)

FACILITY LOCATIONS (Sites)

(b) (7)(F)

(b) (7)(F)

(b) (7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets, if necessary, or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs					0
5. Cats					0
6. Guinea Pigs		14	19	91	124
7. Hamsters		12	144		156
8. Rabbits			272		272
9. Non-human Primates			510	10	520
10. Sheep					0
11. Pigs					0
12. Other Farm Animals					0
13. Other Animals					0
Cotton Rats		16			16
					0
					0

ASSURANCE STATEMENTS

- 1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2.) Each principal investigator has considered alternatives to painful procedures.
- 3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (L.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

NAME AND TITLE OF C.E.O. OR L.O. (Type or Print)

(b) (6), (b) (7)(C)

DATE SIGNED

12/13/17

APHIS FORM 7023  
JUL 2013

19-04205\_000001

Obtained by Rise for Animals. Uploaded 07/06/2020

18 DEC 2017

NP 1/2/18



57 Union Street,  
Worcester, MA 01608  
508 459 7544 [biomere.com](http://biomere.com)

File No. 23918/BRM/0215

December 13, 2017

United States Department of Agriculture, Animal Care  
Eastern Region  
920 Main Campus Drive, Suite 200  
Raleigh, NC 27606-5210

**RE:Annual Report of Research Facility (APHIS Form 7023) Certificate Number 14-R-0192, Amendment to**

Dear Ms. / Sir,

Please refer to our subject report for the current year submitted on November 17, 2017 which may please be discarded. Due to an oversight certain number of animals had not been included under column D of rows 6. The error is being corrected now by this submission.

Enclosed please find revised APHIS Form 7023 and Column E explanations for the reporting period October 01, 2016 – September 30, 2017 in respect of registration number: 14-R-0192.

The information excluding the above remains unchanged.

Sincerely,

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)

cc:

Mark Nedelman, M.S.  
CEO, Biomere

(b) (6), (b) (7)(C)

18 DEC 2017



## Attachment (Item 6)

### Column E Explanation Form

This form is intended as an aid to completing the Column E explanation.

Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. IACUC approved protocol number and date: 15-04, 2/2/15
2. Number of animals used under Column E conditions in this study: 91
3. Species (common name) of animals used in this study: guinea pig
4. Explain the procedure producing pain and/or distress, including reason(s) for species selected. (Cut/paste from the approved docket and or amendments).

Guinea pigs are the major animal infection model established for the human herpes virus-2 (HSV-2) to evaluate protective efficacy of potential HSV-2 vaccines and therapeutic test compounds. The Hartley guinea pig model was chosen to observe clinical signs, body weight and mortality post HSV-2 infection and treatment with potential therapeutic test substances. Post infection, animals were monitored daily for clinical signs of disease. The viral infection of guinea pigs with HSV-2 can have varying clinical readouts from no clinical signs to morbidity. To evaluate the viral disease, we followed the established published literature for viral clinical scoring listed in the table below. Animals that reached a moribund state or exhibited a score of (4) or a loss of 30% body weight were immediately euthanized humanely.

Observation	Score
No clinical signs of disease	0
Vaginal erythema	1
Single to a few modest herpetic lesions	2
Large or fused vesicles	3
Severe vaginal ulceration and paralysis	4
Found dead	5

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.

Analgesics may interfere with immune responses and physiological processes of the infection and the display of disease symptoms and interfere or obscure immune protection results. The measurement of clinical scores is vital to the determination of the efficacy of the vaccine. Therefore, we did not use analgesics that could interfere with test results. For example, morphine is known to suppress the innate immune system and reduce severity of HSV-1 infection; the opioid derivative buprenorphine may have similar effects; the cyclooxygenase-2 (Cox-2) pathway is required for efficient herpes virus replication; NSAIDs down-regulate this pathway and Cox-2 inhibitors limit the replication of herpes viruses; Lidocaine destabilizes the HSV virion. Therefore, animals exhibiting pain or unrelieved distress (reached a moribund state or exhibit a score of 4) or a loss of 30% body weight were immediately euthanized.

Agency None CFR



## Attachment (Item 9)

### Column E Explanation Form

This form is intended as an aid to completing the Column E explanation.

Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

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**1. IACUC approved protocol number and date: 15-16, approved 11/12/15**

**2. Number of animals used under Column E conditions in this study 10**

**3. Species (common name) of animals used in this study *Callithrix jacchus* (common marmoset)**

**4. Explain the procedure producing pain and/or distress, including reason(s) for species selected. (Cut/paste from the approved docket and or amendments).**

Experimental autoimmune encephalomyelitis (EAE) is induced by immunization of animals with human recombinant myelin oligodendrocyte glycoprotein (rhMOG) emulsified in complete Freund's adjuvant (CFA) once on Day 1 by intradermal injection to the back in 2 spots (50 - 100  $\mu$ L/spot). After a variable latency period, animals will develop mild symptoms of EAE (altered vision and gait) followed by rapid progression, including partial to total limb paralysis. Onset of disease symptoms may be associated with pain and distress that was not alleviated to allow for end point analysis (evaluation of Test Article effects). Humane end points were used to minimize possible pain and distress. The marmoset has been published as a reliable NHP model for EAE allowing for efficacy testing of novel biologics that would not be possible to test in small animal species due to immune system cross-reactivity to the test article target and immunogenicity.

**5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.**

Experimental autoimmune encephalomyelitis (EAE) is an autoimmune disease model in which the immune system is triggered to attack a self-component. Treatment with Non-steroid anti-inflammatory drugs (NSAIDs) would alter this immune process and thus compromise the model and purpose of the study.

Agency None CFR

18 DEC 2017



## Inspection Report

Biomedical Research Models Inc  
57-3 Union Street  
Worcester, MA 01608

Customer ID: **23918**

Certificate: **14-R-0192**

Site: 001

BIOMEDICAL RESEARCH MODELS INC

Type: ROUTINE INSPECTION

Date: 28-JUN-2017

There were no AWA regulated research activities at this site of the Registrant at the time of the inspection.

NOTE - Exit briefing held 6/29/17 on-site with facility representatives.

\*END OF REPORT\*

---

**Prepared By:**

GLADUE PAULA, V M D USDA, APHIS, Animal Care

**Date:**  
29-JUN-2017

**Title:** VETERINARY MEDICAL OFFICER 1054

**Received By:**

**Obtained by Rise for Animals. Uploaded 07/06/2020**

**Title:** (b) (6), (b) (7)(C)  
19-04205\_000005 (b) (6), (b) (7)(C)

**Date:**  
29-JUN-2017



Cust No	Cert No	Site	Site Name	Inspection
23918	14-R-0192	001	BIOMEDICAL RESEARCH MODELS INC	28-JUN-17

No Animals were Inspected.

Count	Species
000000	NONE
000000	Total



## Inspection Report

Biomedical Research Models Inc  
57-3 Union Street  
Worcester, MA 01608

Customer ID: **23918**

Certificate: **14-R-0192**

Site: 003

BIOMEDICAL RESEARCH MODELS INC

Type: ROUTINE INSPECTION

Date: 28-JUN-2017

There were no non-compliant items identified during the inspection.

NOTE - Inspection conducted 6/28/17 and 6/29/17. Exit briefing held 6/29/17 on-site with facility representatives.

\*END OF REPORT\*

---

**Prepared By:**

GLADUE PAULA, V M D USDA, APHIS, Animal Care

**Date:**  
29-JUN-2017

**Title:** VETERINARY MEDICAL OFFICER 1054

**Received By:**

**Obtained by Rise for Animals. Uploaded 07/06/2020**

**Title:** (b) (6), (b) (7)(C)  
19-04205\_000007 (b) (6), (b) (7)(C)

**Date:**  
29-JUN-2017



Cust No	Cert No	Site	Site Name	Inspection
23918	14-R-0192	003	BIOMEDICAL RESEARCH MODELS INC	28-JUN-17

Count	Species
000014	RHESUS MACAQUE
000015	DOMESTIC RABBIT / EUROPEAN RABBIT
000298	CRAB-EATING MACAQUE / LONG-TAILED MACAQUE / CYNOMOLGUS MONKEY
<b>000327</b>	<b>Total</b>





United States Department of Agriculture  
Animal and Plant Health Inspection Service  
Teachable Moments

Legal Name: BIOMEDICAL RESEARCH MODELS INC

Customer Number: 23918 Certificate Number: 14-R-0192

Inspection Date: 28-JUN-17 Site Number: 003

Inspector: PAULA GLADUE, V M D

Section: \_\_\_\_\_

**3.80(a)(2)(ii) PRIMARY ENCLOSURES.**

Flexible water lines to the luxits need to be modified to prevent access to the lines by the NHPs.



## Inspection Report

Biomedical Research Models Inc  
57-3 Union Street  
Worcester, MA 01608

Customer ID: **23918**

Certificate: **14-R-0192**

Site: 003

BIOMEDICAL RESEARCH MODELS INC

Type: ROUTINE INSPECTION

Date: 24-JUL-2018

There were no non-compliant items identified during the inspection.

NOTE - Inspection conducted 7/24/18 and 7/25/18. Exit briefing held 7/25/18 on-site with facility representatives.

\*END OF REPORT\*

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**Prepared By:**

GLADUE PAULA, V M D USDA, APHIS, Animal Care

**Date:**  
25-JUL-2018

**Title:** VETERINARY MEDICAL OFFICER 1054

**Received By:**

**Obtained by Rise for Animals. Uploaded 07/06/2020**

**Title:** (b) (6), (b) (7)(C)

**Date:**  
25-JUL-2018

19-04205\_000010  
**Title:** (b) (6), (b) (7)(C)



## Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
23918	14-R-0192	003	BIOMEDICAL RESEARCH MODELS INC	24-JUL-18

Count	Scientific Name	Common Name
000323	<i>Macaca fascicularis</i>	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000028	<i>Macaca mulatta</i>	RHESUS MACAQUE
000053	<i>Oryctolagus cuniculus</i>	DOMESTIC RABBIT / EUROPEAN RABBIT
<b>000404</b>	<b>Total</b>	



United States Department of Agriculture  
Animal and Plant Health Inspection Service  
Teachable Moments

Legal Name: BIOMEDICAL RESEARCH MODELS INC

Customer Number: 23918 Certificate Number: 14-R-0192

Inspection Date: 24-JUL-18 Site Number: 003

Inspector: PAULA GLADUE, V M D

Section: \_\_\_\_\_

**2.31(d)(5) INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).**

The IACUC shall conduct continuing reviews of ongoing activities involving animals at appropriate intervals as determined by the IACUC, but the continuing reviews shall not be conducted less than annually.





## Inspection Report

Biomedical Research Models Inc  
57-3 Union Street  
Worcester, MA 01608

Customer ID: **23918**

Certificate: **14-R-0192**

Site: 001

BIOMEDICAL RESEARCH MODELS INC

Type: FOCUSED INSPECTION

Date: 16-MAY-2019

There were no AWA regulated research activities at this site of the Registrant at the time of the inspection.

NOTE - Exit briefing held 5/16/19 on-site with facility representatives. Report delivered by email 5/16/19.

\*END OF REPORT\*

---

**Prepared By:**

GLADUE PAULA, V M D USDA, APHIS, Animal Care

**Date:**  
16-MAY-2019

**Title:** VETERINARY MEDICAL OFFICER 1054

**Received By:**

**Obtained by Rise for Animals. Uploaded 07/06/2020**

**Title:** REPORT DELIVERED BY EMAIL 5/16/19  
19-04205\_000013

**Date:**  
16-MAY-2019



## Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
23918	14-R-0192	001	BIOMEDICAL RESEARCH MODELS INC	16-MAY-19

No Animals were Inspected.

Count	Scientific Name	Common Name
000000	NONE	NONE
000000	Total	



## Inspection Report

Biomedical Research Models Inc  
57-3 Union Street  
Worcester, MA 01608

Customer ID: **23918**

Certificate: **14-R-0192**

Site: 003

BIOMEDICAL RESEARCH MODELS INC

Type: FOCUSED INSPECTION

Date: 16-MAY-2019

There were no non-compliant items identified during the inspection.

NOTE - Exit briefing held 5/16/19 on-site with facility representatives. Report delivered by e-mail 5/16/19.

\*END OF REPORT\*

**Prepared By:**

GLADUE PAULA, V M D USDA, APHIS, Animal Care

**Date:**  
16-MAY-2019

**Title:** VETERINARY MEDICAL OFFICER 1054

**Received By:**

**Obtained by Rise for Animals. Uploaded 07/06/2020**

**Title:** REPORT DELIVERED BY EMAIL 5/16/19  
19-04205\_000015

**Date:**  
16-MAY-2019



## Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
23918	14-R-0192	003	BIOMEDICAL RESEARCH MODELS INC	16-MAY-19

Count	Scientific Name	Common Name
000262	<i>Macaca fascicularis</i>	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000063	<i>Macaca mulatta</i>	RHESUS MACAQUE
000038	<i>Oryctolagus cuniculus</i>	DOMESTIC RABBIT / EUROPEAN RABBIT
<b>000363</b>	<b>Total</b>	



## Research Facility Protocol Selection Worksheet <sup>\*</sup>

**Legal Name:** Biomedical Research Models Inc

**Customer Number:** 23918

**Certificate Number:** 14-R-0192

**Site Number:** 001 & 003

**Inspection Date:** 5/16/19

**Inspection Type:** Routine ☐ Focused ☒ (list areas inspected)

Animals and Animal Housing; Produce storage; IACUC minutes; Reports to IO; FY 18 USDA AR; 2 protocols

**Inspector:** PSGladue, VMD

Reasons Protocols Were Selected for Review :	How Many Protocols Were Selected
1. Protocols identified during inspection of concern (select all)	0
2. Column E protocols ( select all)	0
3. Protocols with IACUC-approved exemptions/exceptions (select all)	0
4. Protocols cited as noncompliant and not corrected during the last inspection (select all)	0
5. Additional Protocols Selected: a. If <5 remaining protocols, select all remaining:  b. If >5 remaining protocols, select 5 additional protocols: 1) Protocol for each regulated species and/or, 2) Protocols involving high risk procedures (see Chapter 7, Animal Welfare Inspection Guide for guidance):	2
<b>Total Protocols Selected and Reviewed</b>	2

**\*Note:** Protocol selection guidance applies to protocols which have been initially approved, or have had significant changes approved, since the last inspection. For protocols reviewed by an Animal Care Veterinary Medical Officer within the last year, professional judgment should be used in determining whether another review is necessary.

Version 2/11/19

**From:** (b) (6), (b) (7)(C)  
**To:** [Gladue, Paula S - APHIS](#)  
**Subject:** RE: \*\*\*Action required - USDA inspection reports BRM 001 5/16/19 focused & BRM 003 5/16/19 focused  
**Date:** Friday, May 17, 2019 7:45:09 AM

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Hi Paula,  
I received the inspection reports.  
Thanks and have a great weekend

(b) (6), (b) (7)(C)

**From:** Gladue, Paula S - APHIS <paula.s.gladue@usda.gov>  
**Sent:** Thursday, May 16, 2019 8:50 PM  
**To:** (b) (6), (b) (7)(C) <(b) (6), (b) (7)(C)@biomere.com>  
**Subject:** \*\*\*Action required - USDA inspection reports BRM 001 5/16/19 focused & BRM 003 5/16/19 focused  
**Importance:** High

Hi (b) (6), (b) (7)(C),

Here are the inspection and inventory reports from the inspection conducted Thursday 5/16/19 plus the Research Protocol Selection form. Please note that if you are viewing this e-mail on an iPhone that the RPS form may appear blank but is filled out when viewing it on a computer.

I have sent the reports in a PDF format. \*\*\***Please acknowledge within 5 days that you successfully received the inspection reports via a return e-mail to me.**\*\*\* The return e-mail takes the place of a "received by" signature on the reports.

If you are having any difficulty sending an e-mail response, please let me know by calling me at 860-423-6431 and I can send the reports to you by a different method.

Thanks and enjoy the upcoming finally dry weekend!

Paula

Paula S. Gladue, V.M.D.  
USDA/APHIS/Animal Care  
P.O. Box 117; Willimantic; CT 06226  
Office (860) 423-6431

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17 Union Street, Worcester, MA 01608  
508.459.7544 [biomere.com](http://biomere.com)

OCT 02 2017

File No. 23918/BRM/0215

September 27, 2017

Elizabeth Goldentyer, D.V.M.  
Regional Director- USDA, APHIS, Animal Care  
Eastern Region  
920 Main Campus Drive, Suite 200  
Raleigh, NC 27606-5213

14-R-0192  
23918

**RE: Customer ID number: 23918. Change in IACUC Members effective  
September 22, 2017**

Dear Dr. Goldentyer:

This letter is to inform you of changes to our IACUC Roster.

✓ (b) (6), (b) (7)(C) is no longer a member of the Biomere IACUC effective as of September 22, 2017.

✓ (b) (6), (b) (7)(C) has resigned from the Biomere IACUC effective as of October 2, 2017.

✓ (b) (6), (b) (7)(C) has been appointed as a member of the Biomere IACUC effective October 2, 2017. (b) (6), (b) (7)(C) has 20 years' experience working with laboratory rodent models.

This change in the program will be reflected in the 2017 Annual Report.

Sincerely,

(b) (6), (b) (7)(C)

cc:

✓ (b) (6), (b) (7)(C)

✓ (b) (6), (b) (7)(C)



57 Union Street,  
Worcester, MA 01608  
508.459.7144 [biomere.com](http://biomere.com)

File No. 23918/BRM/0215

May 23, 2019

United States Department of Agriculture, Animal Care  
Eastern Region  
920 Main Campus Drive, Suite 200  
Raleigh, NC 27606-5210

**RE: IACUC Member Updates effective May 23, 2019: Certificate Number 14-R-0192.**

This letter is to inform you of changes to Biomere's IACUC Roster.

(b) (6), (b) (7)(C) has been appointed to Biomere's IACUC as a non-affiliated active member for IACUC effective as of May 23, 2019. (b) (6), (b) (7)(C) has served on Biomere's IACUC as the non-affiliated stand-by member for the last 2 years'.

(b) (6), (b) (7)(C) has resigned as IACUC's non-affiliated active member for Biomere effective as of May 23, 2019.

This change in the program will be reflected in the 2019 Annual Report.

Sincerely, /

(b) (6), (b) (7)(C)





57 Union Street Worcester, MA 01608  
508 459 7544 [biomere.com](http://biomere.com)

JUN 14 2017

File No. 23918/BRM/0215

June 13, 2017

Elizabeth Goldentyer, D.V.M.  
Regional Director- USDA, APHIS, Animal Care  
Eastern Region  
920 Main Campus Drive, Suite 200  
Raleigh, NC 27606-5213

**RE: Customer ID number: 23918, (b) (7)(F) 57 Union Street,  
Worcester, MA Facility effective June 15, 2017**

Dear Dr. Goldentyer:

This letter is to inform you of the opening of an additional floor of Biomere's 57 Union Street, Worcester, MA facility. (b) (7)(F)  
(b) (7)(F) The city of Worcester approved an occupancy permit for the area effective June 13, 2017. This brings the total occupied space to (b) (7)(F)

This change in the program will be reflected in the 2017 Annual Report.

Sincerely,

(b) (6), (b) (7)(C)

cc:

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C)