



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

March 12, 2020

Re: Animal Welfare Assurance
A3944-01 [OLAW Case 1P]

Dr. Sandra Harris-Hooker
Vice President and Executive Vice Dean
For Research and Academic Administration
Morehouse School of Medicine –
Atlanta University Center
720 Westview Drive - SW
Atlanta, GA 30310

Dear Dr. Harris-Hooker,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 28, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Morehouse School of Medicine following up on an initial January 24, 2020 notification by telephone.

According to the information provided, this Office understands that the Morehouse School of Medicine Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: the breeding of rats without appropriate IACUC review and approval. The final report states that on January 23, 2020, the IACUC received information that animal breeding was performed without prior IACUC review and approval. The Attending Veterinarian, with the support of the IACUC, requested the PI cease all breeding activity and cede necessary weaning to CLAR staff. No animals were harmed during this process and the PI took responsibility for the noncompliance. The IACUC determined this was an isolated incident and approved the corrective actions listed below.

- The PI agreed to cease breeding and allow CLAR staff to perform weaning if needed until a protocol amendment was reviewed and approved by the IACUC.
- The PI submitted a protocol amendment to add breeding, weaning and genotyping. The amendment was approved by the IACUC on February 27, 2020.

It is noted that this research is supported by PHS funds. Based on its assessment of this explanation, OLAW understands that Morehouse School of Medicine has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM
Veterinary Medical Officer
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



February 28, 2020

Brent Morse, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892

Dear Dr. Morse:

Morehouse School of Medicine, in accordance with Assurance D16-00537_A3944-01 and PHS Policy IV.F.3., provides this final report of noncompliance regarding the discovery of research rat breeding, an activity not reviewed and approved by the IACUC in Principle Investigator (PI) Walter Royal, III, MD's study protocol entitled "Nicotinic Receptor Activation and Brain Proinflammatory Responses in HIV-1 Transgenic Rats." This incident was first reported to Dr. Jacquelyn Tubbs, OLAW, via a phone call on January 24, 2020. The associated NIH funded grant is FOAP: 338005-310001-71008-21.

Situation and Assessment

On January 23, 2020, the IACUC received information that rat breeding was performed without prior IACUC review and approval. No animals were harmed during this process. At the time of the discovery of the noncompliance, the protocol did not describe procedures for breeding or weaning rats. The Attending Veterinarian, with the support of the IACUC, requested the PI cease all breeding activity and cede necessary weaning to CLAR staff. The PI stated that this was an unfortunate oversight and took responsibility for the noncompliance.

The corrective actions to address the situation and approved by the IACUC are detailed as follows:

1. The PI agreed to cease rat breeding and allow CLAR staff to perform weaning if needed until a protocol amendment was reviewed and approved by IACUC.
2. The PI submitted a protocol amendment to add rat breeding, weaning, and genotyping. The amendment was approved by the IACUC on February 27, 2020.

The IACUC determined that this was an isolated incident and not a programmatic failure. The IACUC also believes its investigation was thorough and the corrective actions were appropriate. Should you have any questions regarding this report, please contact Sharon Francis, PhD, IACUC Chair.

Sincerely,

(b) (6)

Sandra Harris-Hooker, PhD
Vice President and Sr. Associate Dean, Research Affairs
Institutional Official
Morehouse School of Medicine

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720 Westview Dr. S.W. • Atlanta, Georgia 30310-1495 • Telephone (404) 752-1725 • Fax (404) 752-1103 • Email: osra@msm.edu

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Monday, March 09, 2020 3:04 PM
To: (b) (6)
Cc: Harris-Hooker, Sandra; Francis, Sharon; (b) (6)
Subject: RE: Morehouse School of Medicine (Assurance #D16-00537) - Report of Noncompliance

Thank you for providing this final report. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: (b) (6)
Sent: Wednesday, March 04, 2020 2:56 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Cc: Harris-Hooker, Sandra <sharris-hooker@msm.edu>; Francis, Sharon <sfrancis@msm.edu>; (b) (6)
Subject: Morehouse School of Medicine (Assurance #D16-00537) - Report of Noncompliance

Good afternoon Dr. Morse,

I am submitting the attached report of noncompliance on behalf of the Morehouse School of Medicine.

Let us know if you need anything else.

Thank you and have a great day!

Warm Regards,

(b) (6)

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Initial Report of Noncompliance

By: [REDACTED] (b) (6)

Date: 01-24-2020

Time: 3:10p

Name of Person reporting:

Telephone #: [REDACTED] (b) (6)

Fax #:

Email: [REDACTED] (b) (6)

Name of Institution: Barnhouse School of Medicine
Assurance number: A3944-01

Did incident involve PHS funded activity? unfure

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Unintentional breeding not currently approved in protocol,

Species involved: rat

Personnel involved: Animal Care Staff

Dates and times: 01-23-2020

Animal deaths: 0

Projected plan and schedule for correction/prevention (if known): _____

30d response expected

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____