



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive B MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

November 22, 2019

Re: Animal Welfare Assurance
#A3160-01 [OLAW Case T]

Ms. Julie Jordan
Interim Vice President for Research and
Economic Development
Mississippi State University
P.O. Box 6343, (b) (4) Lee Hall
Mississippi State, MS 39792

Dear Ms. Jordan,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 20, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Mississippi State University, following up on an initial report on October 17, 2019. According to the information provided, OLAW understands that mice were being bred on a protocol that did not cover this activity.

The corrective actions consisted of approving a new breeding protocol and transferring all breeders to it, amending a second protocol to state that the breeding protocol would be a source of animals for this one, closing expired protocols and replacing them with updated versions, counseling the student overseeing the breeding activities, having the Principal Investigator accept responsibility for all animal records, and ensuring that the animal care staff monitor changes in protocol numbers.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy. Please ensure that no unauthorized charges are made to the NIH grant. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair



MISSISSIPPI STATE
UNIVERSITY™

**Office of the Vice President for
Research and Economic
Development**

November 20, 2019

P.O. Box 6343
3001 Lee Hall
Mississippi State, MS 39762
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Axel Wolff, 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. Wolff:

Mississippi State University, in accordance with Assurance A3160-01 and PHS Policy IV.F.3., provides this report of noncompliance regarding an Investigator who had two mouse protocols: one for breeding and one for research. The breeding protocol (16-575) was used to supply animals for his research protocol (17-033). All animals were identified, through both cage cards and the electronic animal tracking system, as being on the research protocol (17-033). The animals used for the research project were correctly identified; however, some of the animals were used only for breeding and should have been identified as being on the breeding protocol (16-575). Because 17-033 does not have breeding as an approved procedure, this resulted in the conduct of animal-related activities without IACUC approval and failure to adhere to an IACUC-approved protocol.

The funding components associated with these projects are as follows:

<u>Sponsor</u>	<u>MSU Banner Account #</u>	<u>Exp. Date</u>	<u>Award Title</u>
MAFES	266012-012000-027000-384050		(b) (6) Startup
NIH	320666-012000-027000-141030	Expires 8/31/21	Optimized Selenium Intake, Gut Microbiota, and Diabetes

To address the situation, corrective actions have been taken including the approval of a new breeding protocol (19-393) that all breeding animals have been transferred to. Additionally, submission of an amendment to protocol 17-033 was submitted and approved to add protocol 19-393 as a source of animals.

The PI has accepted full responsibility for accurate records for his project, including cage cards, census records, etc. The IACUC determined that this was an isolated incident and not an issue of repeat noncompliance.

The following corrective action plan was implemented after the incident:

1. Because protocol 16-575 was expiring soon, it was closed.
2. A new breeding protocol has been approved, and all breeding animals have been transferred to this new protocol, 19-393.
3. Protocol 17-033 has been amended to add protocol 19-393 as a source of animals. No breeding animals are allowed on 17-033.
4. Protocol 17-033 will be closed by the end of the year and replaced by a new, updated protocol.

5. The PI has discussed this issue with the graduate student who was handling the breeding colony and who was creating new cage cards as animals were weaned and transferred to a project.
6. The PI has accepted full responsibility for accurate records for his project, including cage cards, census records, etc.
7. The animal care staff will be vigilant in recognizing changes in protocol numbers.

At the IACUC meeting on November 19, 2019, the IACUC reviewed and accepted the corrective action plan.

Mississippi State is committed to protecting the welfare of animals use in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Brian Rude, PhD, IACUC Chair at (b) (6) or by email at brude@ads.msstate.edu.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Julie Jordan

Interim Vice President for Research and Economic Development

cc: Ms. Kacey Strickland, Director of Research Compliance
Dr. Brian Rude, Chair, IACUC

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, November 22, 2019 11:11 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final Report of Noncompliance by (b) (6)

Thank you for this report, (b) (6) We will respond soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6)
Sent: Friday, November 22, 2019 10:38 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Rude, Brian <BRude@ads.msstate.edu>; (b) (6)
(b) (6) Strickland, Kacey <kstrickland@orc.msstate.edu>; (b) (6)
(b) (6)
Subject: Final Report of Noncompliance by (b) (6)

Please see the attached Final Report on Noncompliance from Mississippi State University.

(b) (6)

Preliminary Report to OLAW

Name & Contact:

(b) (6)

Institution

Mississippi State University

Assurance Number:

Assurance # A3160-01

Funding Components:

<u>Sponsor</u>	<u>MSU Banner Account #</u>	<u>Exp. Date</u>	<u>Award Title</u>
MAFES	266012-012000-027000-384050		(b) (6) Startup
NIH	320666-012000-027000-141030	Expires 8/31/21	Optimized Selenium Intake, Gut Microbiota, and Diabetes

Brief Description of Incident:

An Investigator had two mouse protocols: one for breeding and one for research. The breeding protocol (16-575) was used to supply animals for his research protocol (17-033). All animals were identified, through both cage cards and the electronic animal tracking system, as being on the research protocol (17-033). The animals used for the research project were correctly identified; however, some of the animals were used only for breeding and should have been identified as being on the breeding protocol (16-575). Because 17-033 does not have breeding as an approved procedure, this resulted in the conduct of animal-related activities without IACUC approval and failure to adhere to an IACUC-approved protocol.

Plan and Schedule for Correction & Prevention:

1. Because protocol 16-575 was expiring soon, it was closed.
2. A new breeding protocol has been approved, and all breeding animals have been transferred to this new protocol, 19-393.
3. Protocol 17-033 has been amended to add protocol 19-393 as a source of animals. No breeding animals are allowed on 17-033.
4. Protocol 17-033 will be closed by the end of the year and replaced by a new, updated protocol.
5. The PI has discussed this issue with the graduate student who was handling the breeding colony and who was creating new cage cards as animals were weaned and transferred to a project.
6. The PI has accepted full responsibility for accurate records for his project, including cage cards, census records, etc.
7. The animal care staff will become for vigilant in recognizing changes in protocol numbers.

Time Frame for Final Report from IO: December 15, 2019

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, October 18, 2019 7:16 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Preliminary Report for Non-Compliance Issue @ MS State University

Thank you for this report, (b) (6) We will open a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6)
Sent: Thursday, October 17, 2019 4:03 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Rude, Brian <BRude@ads.msstate.edu>; (b) (6) Strickland, Kacey
<kstrickland@orc.msstate.edu>
Subject: Preliminary Report for Non-Compliance Issue @ MS State University

Attached please find a preliminary report of a non-compliance issue that occurred at our institution. Please feel free to contact us if you have any additional questions. Thanks.

(b) (6)

