



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) 402-7065

November 6, 2019

Re: Animal Welfare Assurance  
#A3180-01 (OLAW Case 5M)

Dr. Todd Sherer  
Interim Vice President for  
Research Administration  
Emory University  
1599 Clifton Road, NE, 4<sup>th</sup> Floor  
Atlanta, Georgia 30322-1599

Dear Dr. Sherer,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 30, 2019 letter reporting a noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at Emory University. Your letter supplements the information provided in the initial email report on July 17, 2019. According to the information provided it is understood that on [July] 17, 2019 the IACUC suspended an animal activity due to the accumulation of deficiency points. The points were the result of **incomplete surgery records, incorrect sexing of animals, improperly labeled reagents, improper storage and/or sterilization of analgesia agents, improper post-operative monitoring, use of expired controlled substances, and improper documentation of the use of controlled substances.** The animals were assigned to a PHS-funded activity (1R01HL138423-01).

On August 7, 2019 the breeding and colony maintenance parts of the protocol were reactivated. The IACUC required that the PI and lab surgeon must complete surgery retraining, and all surgeries must be conducted under DAR supervision.

On August 21, 2019 the protocol was fully reinstated. The IACUC required that the PI submit an amendment indicating how certain reagents will be prepared, the PI will follow the University's policy on injectable agents, the PI will monitor all surgery animals per University policy, the lab will no longer use expired analgesia and anesthesia agents and, the PI submit an amendment addressing the mandatory items detailed in the surgical retraining assessment.

On September 5, 2019 it was reported that the PI conducted surgery on a mouse without DAR supervision and without the approved protocol amendment.

On September 18, 2019 the IACUC suspended all surgical activities. The IACUC required that the PI be counseled and abide by previous requirements.

On October 16, 2019 the IACUC reinstated all surgical activities.

Further corrective and preventive actions consisted of the PI participating in PAM visits and reading specific IACUC policies deemed by the committee.

OLAW believes that the corrective and preventive measures put in place by Emory University are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact  
Taryn Cobb, Grants Management Specialist, NHLBI



EMORY  
UNIVERSITY

Institutional Animal Care and Use Committee

October 30, 2019

Brent Morse DVM  
Acting Director, Division of Compliance  
Oversight Office of Laboratory Animal Welfare  
National Institutes of Health  
RKL 1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982  
Re: Emory University, Animal Welfare Assurance #A3180-01

Dear Dr. Morse,

The Emory University Institutional Animal Care and Use Committee (IACUC), through the Institutional Official, is reporting the results of an event as required by section IV, F, 3a of the *Public Health Service Policy on Humane Care and Use of Laboratory Animals* (PHS Policy). A preliminary report was provided via email to your office on July 17, 2019. This is the final report regarding a suspension of a Principal Investigator's (PI) animal use activities and protocol. The associated NIH-funded grant is NIH 1R01 HL138423-01.

#### Situation and Assessment

On March July 17, 2019, due to an accumulation of deficiency points, the University's IACUC Committee approved a suspension of PI's animal use activities and associated protocol. Please see the timeline below.

1. On January 8, 2019, during a semi-annual inspection of the lab's facility, it was discovered that the lab had incomplete surgery records. The PI and lab were assigned 2 deficiency points for this non-compliance.
2. On January 15, 2019, 12 mice from the lab died due to incorrect sexing of the animals. The PI and lab were assigned 4 deficiency points for this non-compliance which was reported to OLAW on May 27, 2019.
3. On July 7, 2019, during a semi-annual inspection of the lab's facility, the following issues resulted in the accumulation of 14 deficiency points for the lab.
  - Improperly labeled reagents
  - Improper storage and/or sterilization of analgesia agents
  - Improper post-operative monitoring of survival surgeries
  - Use of expired controlled substances
  - Improper documentation of the use of controlled substances

According to the University's guidelines, the accumulation of 12 or more points during a 1 year rolling period can result in the suspension of a lab and/or protocol.

4. On August 7, 2019, upon review of materials and responses submitted by the PI related to the

suspension, the IACUC Committee voted to reactivate the protocol for breeding and colony maintenance only. This determination was based on the PI following the listed action items below, which were required by the IACUC Committee.

- The PI and lab surgeon must complete surgery re-training
  - All surgeries (both survival and non-survival) must be conducted under DAR supervision
  - A plan will need to be provided on how the PI and lab will communicate with DAR in regard of scheduling surgeries
5. On August 21, 2019, upon review of materials and responses submitted by the PI related to the partial suspension, the IACUC Committee voted to fully reinstate the protocol. This determination was based on the PI following the listed action items below, which were required by the IACUC Committee.
- The PI will need to submit an amendment indicating how certain reagents will be prepared
  - The PI will follow the University's policy on injectable agents with regards to maintenance of sterility and storage
  - The PI will monitor all surgery animals per the University's Aseptic Survival Surgery in Rodents policy
  - The lab will no longer use expired analgesia and anesthesia agents for any surgeries
  - An amendment to address the mandatory items detailed in the surgical re-training assessment must be approved prior to reinitiating surgeries
  - Surgeries performed by the lab must be performed under DAR supervision
6. On September 5, 2019, DAR veterinarian staff reported that the PI conducted surgery on a mouse without DAR supervision and without the stipulated approved surgical protocol amendment.
7. On September 18, 2019, these findings were presented to the IACUC Committee and it was voted unanimously to suspend all surgical activities. The IACUC Committee provided the following corrective actions that were to be completed by the PI before any surgical activities could resume.
- The PI will submit a point-by-point description of how the lab will conform with the findings from a surgery proficiency assessment
  - The PI will provide DAR with scheduled surgeries and will have all surgeries observed by DAR vet staff
  - A meeting will occur with the PI, IACUC administration and the PI's Departmental Chair
8. On October 16, 2019, upon materials and responses submitted by the PI related to the surgical suspension, the IACUC Committee voted to reinstate all surgical activities associated with the protocol.

**The corrective actions to prevent recurrences are detailed as follows:**

1. The PI will continue to conduct surgeries with DAR observation until further notice is given by the IACUC Committee.
2. The PI will participate in Post-Approval Monitoring (PAM) visits as scheduled until further notice is given by the IACUC Committee.
3. The PI will read specific IACUC policies deemed by the IACUC Committee, will confirm in writing

that the policies were read, and will adhere to the policies.

The IACUC believes its investigation of this incident was thorough and the corrective actions appropriate to prevent a similar occurrence. If you have questions regarding this incident, please contact me or Dr. David Martin, Director, IACUC Office.

Sincerely,

(b) (6)

Todd Sherer; PhD  
Interim Vice President for Research Administration  
Emory University

Cc: Jeff Boatright, IACUC Chair; AAALAC

**Morse, Brent (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, October 30, 2019 11:03 AM  
**To:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Martin, W David  
**Subject:** RE: Final Notification Emory University (Assurance #A3180-01)

Thank you for providing this final report (b) (6) 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, October 30, 2019 10:19 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6) Martin, W David <dwmarti@emory.edu>  
**Subject:** Final Notification Emory University (Assurance #A3180-01)

To Whom It May Concern,

Please accept this final report of a suspension of animal activities and Principal Investigator's protocol at Emory University (Assurance #A3180-01). If there are any questions or concerns, please feel free to contact me.

Best,  
(b) (6)

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A3180-5M

**Morse, Brent (NIH/OD) [E]**

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**From:** Martin, W David <dwmarti@emory.edu>  
**Sent:** Thursday, July 18, 2019 12:22 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD); (b) (6)  
**Cc:** (b) (6)  
**Subject:** RE: [External] RE: Preliminary Notification Emory University (Assurance #A3180-01)

Thank you for the feedback. Our Office of Sponsored projects is aware of the situation and will be working alongside us to provide all the relevant information to the Grants Managers.

Dave

W. David Martin PhD, CPIA  
Director, Institutional Animal Care and Use Committee (IACUC)  
Phone: (b) (6)  
Email: [dwmarti@emory.edu](mailto:dwmarti@emory.edu)  
Internet: <http://www.iacuc.emory.edu/>

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**From:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Sent:** Thursday, July 18, 2019 11:12 AM  
**To:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Martin, W David <dwmarti@emory.edu>  
**Subject:** [External] RE: Preliminary Notification Emory University (Assurance #A3180-01)

Thank you for this report Dr. Martin. We will open a case file and await the final report. Please be sure to notify the Grants Manager for the NIH funding institute about the suspension and explain in the final report regarding that notification.

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, July 17, 2019 4:06 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Martin, W David <dwmarti@emory.edu>; (b) (6)  
**Subject:** RE: Preliminary Notification Emory University (Assurance #A3180-01)



To Whom It May Concern,

Please accept this preliminary notification of a rodent health and welfare concern at Emory University (Assurance #A3180-01). An incident occurred where due to an accumulation of deficiency points, Emory University's IACUC approved a complete suspension of PI's lab and protocol. The NIH grant associated with this protocol is 1R01 HL138423-01. This investigation is ongoing and corrective actions are still being completed. A final report will be upcoming.

W. David Martin PhD, CPIA  
Director, Institutional Animal Care and Use Committee (IACUC)  
Phone: (b) (6)  
Email: [dwmarti@emory.edu](mailto:dwmarti@emory.edu)  
Internet: <http://www.iacuc.emory.edu/>

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## Morse, Brent (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Tuesday, July 23, 2019 7:42 AM  
**To:** Cobb, Taryn (NIH/NHLBI) [E]; OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: [External] RE: Preliminary Notification Emory University (Assurance #A3180-01)

Good morning Ms. Cobb,

Below I have copied and highlighted the specific part of the applicable Notice found at :  
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-081.html> . The grantee should provide you assurance that the grant has not been charged during the period of suspension.

### **Background**

*As previously noted in Notice NOT-OD-07-044, the Office of Management and Budget Cost Principles and the NIH Grants Policy Statement (NIHGPS) do not permit charges to grant awards for the conduct of live vertebrate animal activities during periods of time that the terms and conditions of the NIHGPS are not upheld. Specific situations under which charges are not allowable are:*

- 1. The conduct of animal activities in the absence of a valid Animal Welfare Assurance on file with OLAW.*
- 2. The conduct of animal activities in the absence of a valid Institutional Animal Care and Use Committee (IACUC) approval of the activity. Absence of IACUC approval includes failure to obtain IACUC approval, expiration, or suspension of IACUC approval.*

*Institutions are required to report such situations to the Institute/Center (IC) supporting the award and to OLAW. In cases where charges have been made for unauthorized animal activities, appropriate adjustments must be made to the grant to remove those charges. Consultation with the IC is encouraged regarding questions concerning allowable costs. Funding components may allow expenditure of NIH grant funds for maintenance and care of animals on a case-by-case basis.*

Please feel free to call me if I can be of further assistance.

Best regards, Brent Morse 301-594-2921

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

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**From:** Cobb, Taryn (NIH/NHLBI) [E]  
**Sent:** Monday, July 22, 2019 2:37 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** RE: [External] RE: Preliminary Notification Emory University (Assurance #A3180-01)

Hello Mr. Morse,

The Office of Sponsored Programs from Emory University informed us of the current IACUC suspension for this grant per your instruction. Can you please advise what action if any is required by us? Any guidance would greatly appreciated.

Thank you,  
Taryn

## Taryn Cobb

Grants Management Specialist  
The National Heart, Lung, and Blood Institute  
6701 Rockledge Drive, RM 7162  
Bethesda, MD 20892  
Email: [taryn.cobb@nih.gov](mailto:taryn.cobb@nih.gov)

**From:** Martin, W David <[dwmarti@emory.edu](mailto:dwmarti@emory.edu)>

**Sent:** Thursday, July 18, 2019 12:22 PM

**To:** OLAW Division of Compliance Oversight (NIH/OD) <[olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)>; (b) (6)

**Cc:** (b) (6)

**Subject:** RE: [External] RE: Preliminary Notification Emory University (Assurance #A3180-01)

Thank you for the feedback. Our Office of Sponsored projects is aware of the situation and will be working alongside us to provide all the relevant information to the Grants Managers.

Dave

W. David Martin PhD, CPIA  
Director, Institutional Animal Care and Use Committee (IACUC)  
Phone: (b) (6)  
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**From:** OLAW Division of Compliance Oversight (NIH/OD) <[olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)>

**Sent:** Thursday, July 18, 2019 11:12 AM

**To:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD) <[olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)>

**Cc:** Martin, W David <[dwmarti@emory.edu](mailto:dwmarti@emory.edu)>

**Subject:** [External] RE: Preliminary Notification Emory University (Assurance #A3180-01)

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Director  
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National Institutes of Health

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**From:** [REDACTED] (b) (6)  
**Sent:** Wednesday, July 17, 2019 4:06 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Martin, W David <dwmarti@emory.edu>; [REDACTED] (b) (6)  
**Subject:** RE: Preliminary Notification Emory University (Assurance #A3180-01)

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W. David Martin PhD, CPIA  
Director, Institutional Animal Care and Use Committee (IACUC)  
Phone: [REDACTED] (b) (6)  
Email: [dwmarti@emory.edu](mailto:dwmarti@emory.edu)  
Internet: <http://www.iacuc.emory.edu/>

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