



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Office of Laboratory Animal Welfare  
Rockledge One, Suite 360  
6705 Rockledge Drive - 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

May 7, 2018

Re: Animal Welfare Assurance  
A3310-01 [OLAW Case 1L]

Dr. Phillip Cunningham  
Assistant Vice President for Research  
Wayne State University  
5700 Cass Ave., Suite (b) (4)  
Detroit, MI 48202

Dear Dr. Cunningham,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 27, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Wayne State University. Your final report supplements the information in your prompt preliminary report submitted to this office on September 26, 2017. According to the information provided, OLAW understands that for the period of August 28 – September 3, 2017 the IACUC determined that unapproved surgical procedures were conducted on two rats. On September 1, 2017 three rats were not administered the IACUC approved analgesic regimen for an approved major survival surgery. Veterinary technicians intervened the next morning and provided analgesics and supportive care. After veterinary evaluation, one animal was euthanized and two animals were recovering under veterinary care. The PIs agreed to voluntarily stop all animal activities on September 15, 2017 at the request of the IACUC Chair. Animals were transferred to the IACUC holding protocol and the Division of Laboratory Animal Resources (DLAR) has assumed all daily care responsibilities. This animal activity is funded by NSF grant proposal number 1711409.

Corrective and preventive measures included discussions between you as the Institutional Official and the researchers' Departmental Chair. In addition, the Attending Veterinarian and the IACUC Chair met with the PI and Co-Investigator. The protocol expired on March 31, 2018 and a subsequent protocol was submitted to the IACUC and is undergoing review. Future animal activities will require a meeting between the Attending Veterinarian, the IACUC Chair, the PI and the lab members to discuss protocol compliance including specific procedures and analgesics described in the protocol. The investigative group will be required to notify DLAR animal care staff prior to initiating individual procedures for observation. Follow-up, to include medical records review, will also be conducted.

The prompt consideration of this matter by Wayne State University was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to resolve the issue were appropriate and the on-going oversight to prevent recurrence is expected to be effective. We appreciate being informed of this matter and find no cause for further action by this office.

*Page 2 – Dr. Cunningham*  
*May 7, 2018*  
*OLAW Case A3310-1L*

Sincerely,

(b) (6)

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

cc: IACUC Contact  
NSF Animal Welfare Officer



Philip R. Cunningham, Ph.D.  
Associate Vice President for Research  
Wayne State University  
5057 Woodward Avenue, Suite 2317  
Detroit, MI 48202

(313) 577-9064  
philc@wayne.edu

April 27, 2018

**Animal Welfare Assurance Number: A3310-01**

Brent Morse, DVM, DACLAM  
Acting Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982  
[olawdco@mail.nih.gov](mailto:olawdco@mail.nih.gov)

RE: Follow-up Report: IACUC mandated suspension of animal activities

Principal Investigator: Mark Ming-Cheng Cheng, Ph.D.  
NSF Grant: Parity-Time Symmetric Wireless Telemetry Systems for Implantable Microsensors  
(proposal number 1711409)

Dear Dr. Morse,

I am writing to file a followup report to the above reported IACUC-mandated suspension of September 20, 2017.

History: At the time of the initial report – we laid out the following generalized plan of action for resolution for the unapproved surgical procedures and administration of off-protocol analgesic regimen(s) for an approved major survival surgery procedure: "Planned measures include discussions with the researchers involved, with their Department Chair, the Institutional Official, the IACUC, and Attending and Clinical Veterinarians. During the period of suspension, the animals under A 03-05-15 have been maintained on the IACUC holding protocol and the Division of Laboratory Animal Resources (DLAR) has assumed all daily care responsibilities".

Current status: The Institutional Official met with the Department Chair to discuss suspension and potential resolution. The Attending Veterinarian and IACUC Chair met with the PI and Co-Investigator on November 16th, 2017, to develop an action plan for restoration of the protocol including -- submission of an updated protocol to cover refinements to studies originally detailed and approved in A 03-05-15.

The renewal protocol was submitted to the IACUC as 17-06-0289 in November 2017. Investigator responses to questions posed during the veterinary pre-review are still pending. WSU IACUC protocol A 03-05-15 subsequently expired on March 31<sup>st</sup>, 2018, leaving this project in limbo.

The PI submitted a subsequent protocol (17-05-0278) and the IACUC tabled it after full committee review at the February 2018 meeting. The PI was provided with detailed guidance for revision of the protocol. A revision was received on April 10, 2018, and it is currently undergoing review. There have been no active animal studies from the time of suspension to present.

As a component of the approval process for each of the pending animal use protocols, the Attending Veterinarian and IACUC Chair will meet with the PI and lab members to discuss specific procedures and analgesics described in the protocols and reiterate the requirement to adhere to them strictly. Additionally, the investigative group will be required to notify DLAR animal care staff prior to initiating individual procedures. The procedures will be observed and follow-up, including review of medical records, will be conducted to ensure ongoing compliance. This process will be continued until the Attending Veterinarian and IACUC Chair are satisfied that the laboratory understands and is proficient in the need to adhere to the protocol.

Wayne State University works to maintain the highest standards in our missions. We believe the actions we are taking are appropriate. We would appreciate further guidance on this event, should you feel that it is appropriate.

If you have any questions, please email me at the address above.

Sincerely,

(b) (6)

Philip R. Cunningham, Ph.D.  
Institutional Official

c.c. Dr. James Swearingen, Global Director, AAALAC International, [accredit@AAALAC.org](mailto:accredit@AAALAC.org)  
Dr. Shubhra Gangopadhyay, [sgangopa@nsf.gov](mailto:sgangopa@nsf.gov), NSF Program Official  
Jessie Richardson, [jrichard@nsf.gov](mailto:jrichard@nsf.gov), NFS Grant Official

**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, April 30, 2018 6:58 AM  
**To:** Philip Cunningham  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Followup report

Thank you for this report, Dr. Cunningham. We will send a response soon.

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

-----Original Message-----

**From:** Philip Cunningham [mailto:philc@wayne.edu]  
**Sent:** Friday, April 27, 2018 6:45 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** sgangopa@nsf.gov; jrichard@nsf.gov; International Aaalac <accredit@aaaalac.org>; Lisa Polin <ac8694@wayne.edu>;  
(b) (6)  
**Subject:** Follow-up report

Please see the attached follow-up report to an IACUC-mandated suspension initial report.

If you have any questions, please don't hesitate to contact me.

Sincerely,  
Phil

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Philip R. Cunningham, Ph.D.  
Associate Vice President  
Research Integrity  
Wayne State University  
5057 Woodward Avenue, (b) (4)  
Detroit, MI 48202

Phone: (b) (6)  
FAX: (b) (6)  
Email: philc@wayne.edu

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, April 25, 2018 9:39 AM  
**To:** Philip Cunningham; OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Protocol suspension notification

Thank you for this update Dr. Cunningham.

Sincerely, Brent Morse

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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

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**From:** Philip Cunningham [mailto:philc@wayne.edu]  
**Sent:** Tuesday, April 24, 2018 4:29 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** Re: Protocol suspension notification

Dear Dr. Morse,

We are working on the final report now and expect to have it by the end of the week. This has taken longer than expected and I apologize for not updating you sooner.

Best regards,  
Phil

---

Philip R. Cunningham, Ph.D.  
Associate Vice President  
Research Integrity  
Wayne State University  
5057 Woodward Avenue, (b) (4)  
Detroit, MI 48202

Phone: (b) (6)  
FAX: (b) (6)  
Email: [philc@wayne.edu](mailto:philc@wayne.edu)

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On Apr 23, 2018, at 12:37 PM, OLAW Division of Compliance Oversight (NIH/OD)  
<[olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)> wrote:

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

---

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, April 23, 2018 12:37 PM  
**To:** 'Philip Cunningham'  
**Subject:** RE: Protocol suspension notification

Hello Dr. Cunningham,

We do not appear as of yet to have a final report. If it was sent, please let me know. If not, do you have an interim report available? Thank you.

Regards, Brent Morse

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

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**From:** Philip Cunningham [mailto:philc@wayne.edu]  
**Sent:** Wednesday, September 27, 2017 8:25 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** sgango@nsf.gov; jrichard@nsf.gov; (b) (6)  
(b) (6) ethiels@nsf.gov  
**Subject:** Re: Protocol suspension notification

Thank you, Dr. Morse. Yes, we intend to send a final report ASAP.

Best regards,  
Phil

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Philip R. Cunningham, Ph.D.  
Associate Vice President  
Research Integrity  
(b) (4) Maccabees Building  
5057 Woodward Ave.  
Detroit, MI. 48202

(b) (6)  
[philc@wayne.edu](mailto:philc@wayne.edu)

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On Sep 27, 2017, at 8:18 AM, OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> wrote:

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

---

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, September 27, 2017 9:28 AM  
**To:** 'ethiels@nsf.gov'  
**Subject:** FW: Protocol suspension notification  
**Attachments:** OLAW IACUC suspension\_A 03-05-15.pdf

Hi Flo,

Sorry about that. I should have forwarded the letter to you. PI and grant # are in the letter. I will copy you on the final letter as usual. I thought you should be copied on the preliminary this time since others at NSF were copied by Wayne State.

Regards, Brent

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

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**From:** Philip Cunningham [mailto:philc@wayne.edu]  
**Sent:** Tuesday, September 26, 2017 6:44 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** International Aaalac <accredit@aaalac.org>; sgangopa@nsf.gov; jrichard@nsf.gov; (b) (6)  
(b) (6) Lisa Polin <polinl@karmanos.org>; (b) (6)  
**Subject:** Protocol suspension notification

Please see the attached notification of a protocol suspension. If you have any questions, please do not hesitate to contact me.

Sincerely,  
Phil

---

Philip R. Cunningham, Ph.D.  
Associate Vice President  
Research Integrity  
Wayne State University  
5057 Woodward Avenue, (b) (4)  
Detroit, MI 48202

Phone: (b) (6)  
FAX: (b) (6)  
Email: [philc@wayne.edu](mailto:philc@wayne.edu)

---



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

---

**From:** Philip Cunningham <philc@wayne.edu>  
**Sent:** Wednesday, September 27, 2017 8:25 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** sgangopa@nsf.gov; jrichard@nsf.gov; [REDACTED] ethiels@nsf.gov  
**Subject:** Re: Protocol suspension notification

Thank you, Dr. Morse. Yes, we intend to send a final report ASAP.

Best regards,  
Phil

---

Philip R. Cunningham, Ph.D.  
Associate Vice President  
Research Integrity  
[REDACTED] Maccabees Building  
5057 Woodward Ave.  
Detroit, MI. 48202

[REDACTED]  
[philc@wayne.edu](mailto:philc@wayne.edu)

---

On Sep 27, 2017, at 8:18 AM, OLAW Division of Compliance Oversight (NIH/OD) <[olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)> wrote:

Thank you for this notification Dr. Cunningham. We will use it as a prompt preliminary report. Please send a final report once you have developed the plan to ensure animal welfare. If you have any questions, please let me know.

Regards, Brent Morse

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

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**From:** Philip Cunningham [<mailto:philc@wayne.edu>]  
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**To:** OLAW Division of Compliance Oversight (NIH/OD) <[olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)>  
**Cc:** International Aalac <[accredit@aalac.org](mailto:accredit@aalac.org)>; sgangopa@nsf.gov; jrichard@nsf.gov; [REDACTED] (b) (6)  
[REDACTED] (b) (6) Lisa Polin <[polinl@karmanos.org](mailto:polinl@karmanos.org)>; [REDACTED] (b) (6)  
[REDACTED] (b) (6)  
**Subject:** Protocol suspension notification

Please see the attached notification of a protocol suspension. If you have any questions, please do not hesitate to contact me.

Sincerely,  
Phil

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Philip R. Cunningham, Ph.D.  
Associate Vice President  
Research Integrity  
Wayne State University  
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(313) 577-9064  
philc@wayne.edu

September 26, 2017

**Animal Welfare Assurance Number: A3310-01**

Brent Morse, DVM, DACLAM  
Acting Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982  
[olawdco@mail.nih.gov](mailto:olawdco@mail.nih.gov)

RE: IACUC mandated suspension of animal activities

Principal Investigator: Mark Ming-Cheng Cheng, Ph.D.  
NSF Grant: Parity-Time Symmetric Wireless Telemetry Systems for Implantable Microsensors  
(proposal number 1711409)

Dear Dr. Morse,

I am writing to report an IACUC-mandated suspension of WSU animal protocol A 03-05-15 associated with the NSF grant listed above; due to off-protocol events reported at the most recently convened IACUC meeting of September 20<sup>th</sup>, 2017. The non-compliance concerns occurred during the Aug 28-Sept 3 period: Unapproved surgical procedures were performed on Aug 28<sup>th</sup> on two rats that were subsequently evaluated by veterinarians and euthanized. On Sept 1<sup>st</sup>, three rats were not administered the IACUC approved analgesic regimen for an approved major survival surgery procedure. These surgeries occurred in the early evening and when veterinary technicians evaluated the next morning, they promptly intervened and provided analgesics and supportive care. One of three animals was euthanized post veterinary evaluation; the remaining two animals are recovering under ongoing veterinary care. The IACUC chair requested a voluntary suspension on Sept 11<sup>th</sup>, and after several subsequent discussions, the PIs agreed to voluntarily suspend all animal activities on Sept 15<sup>th</sup> until the full IACUC could convene on Sept 20<sup>th</sup>, 2017 to conduct a review and make a determination.

Collection and documentation of all off-protocol events are continuing in preparation to develop a comprehensive plan to ensure animal welfare with a proactive resolution. Planned measures include discussions with the researchers involved, with their Department Chair, the Institutional Official, the IACUC and Attending and Clinical Veterinarians. During the period of suspension the animals under A 03-05-15 have been placed on the IACUC holding protocol and the Division of Laboratory Animal Resources (DLAR) has assumed all daily care responsibilities.

Sincerely,

  
Philip R. Cunningham, Ph.D.

c.c. Dr. James Swearingen, Global Director, AAALAC International, [accredit@AAALAC.org](mailto:accredit@AAALAC.org)  
Dr. Shubhra Gangopadhyay, [sgangopa@nsf.gov](mailto:sgangopa@nsf.gov), NSF Program Official  
Jessie Richardson, [jrichard@nsf.gov](mailto:jrichard@nsf.gov), NFS Grant Official

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, September 27, 2017 8:19 AM  
**To:** Philip Cunningham; OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** sgangopa@nsf.gov; jrichard@nsf.gov; (b) (6) ethiels@nsf.gov  
**Subject:** RE: Protocol suspension notification

Thank you for this notification Dr. Cunningham. We will use it as a prompt preliminary report. Please send a final report once you have developed the plan to ensure animal welfare. If you have any questions, please let me know.

Regards, Brent Morse

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

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**Cc:** International Aalac <accredit@aaalac.org>; sgangopa@nsf.gov; jrichard@nsf.gov; (b) (6)  
(b) (6) Lisa Polin <polinl@karmanos.org>; (b) (6)  
**Subject:** Protocol suspension notification

Please see the attached notification of a protocol suspension. If you have any questions, please do not hesitate to contact me.

Sincerely,  
Phil

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Philip R. Cunningham, Ph.D.  
Associate Vice President  
Research Integrity  
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5057 Woodward Avenue, (b) (6)  
Detroit, MI 48202

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FAX: (b) (6)  
Email: [philc@wayne.edu](mailto:philc@wayne.edu)

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