



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 – 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

March 29, 2017

Re: Animal Welfare Assurance
A4729-01 [OLAW Case A]

Dr. Kevin Archer
Dean of Graduate Studies and Research
Central Washington University
400 East University Way
Ellensburg, WA 98926

Dear Dr. Archer

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of a copy of your March 13, 2017 letter to Ms. Carow reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Central Washington University. Your letter supplements the information contained in the initial prompt report letter dated October 24, 2016 from Dr. Irwin received by fax on October 25th. According to the information provided, OLAW understands that the PI of protocol no. A081401 had exceeded the number of hamsters approved on his protocol. He was approved to use up to 365 hamsters and as of 10/21/2016 he had used 661. It was stated that the protocol to which the hamsters were assigned received PHS funding via NIH grant 1R15AT008546-01.

Corrective and preventive actions included the IACUC interviewing the PI. The IACUC also terminated the PI's hamster protocol effective 10/27/2016. Care for any remaining animals was taken over by department staff. The PI has submitted subsequent protocols which have either been approved by the IACUC or are still under review. In addition, the PI has changed how animals are accounted for in his laboratory as directed by the IACUC. The PI has also undergone additional training. The IACUC and researchers have developed a standard form to document/track animals moving through the animal care and use program. The new on-line protocol application system will allow anyone listed as a participant on a protocol the ability to view the protocol.

The consideration of this matter by Central Washington University was consistent with the philosophy of institutional self-identification and self-regulation. Similarly, the actions taken to resolve the issue were appropriate and would be expected to correct the noncompliance and prevent a recurrence. We appreciate being informed of this matter and find no cause for further action by this office at this time.

Sincerely,

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

cc: IACUC Contact

Dr. Robert M. Gibbens, Director Western Sector, USDA, APHIS, AC
Shelly Carow, Chief Grants Manager, NCCIH

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Tuesday, March 28, 2017 8:59 AM
To: 'Jason Irwin'
Subject: RE: Question about allowable costs with non-compliance

Hello Dr. Irwin,

To determine which expenditures are allowable, I suggest you contact Joel Snyderman at snydermanj@od.nih.gov. He is very knowledgeable about these issues and can best direct your grants office.

Regards, Brent Morse

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

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From: Jason Irwin [<mailto:IrwinJ@cwu.edu>]
Sent: Monday, March 27, 2017 7:09 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: Question about allowable costs with non-compliance

Hi Brent,

You recently received a final report from Central Washington University regarding a non-compliance event. Our grants office is working through expenditures (incurred before the research was stopped) and wonder what costs are allowable (NIH grant). Is this something you can help us with? Or are there others in your division that can help us with these issues?

If you'd like to discuss this over the phone, please suggest a time to call. I will be in my office on Tuesday morning.

Many Thanks,
 - Jason

Jason Irwin, PhD
 IACUC Chair
 Professor, Biological Sciences
 MS-7537, 400 E. University Way
 Central Washington University
 Ellensburg, WA 98926
 Ph. Phone Number
irwinj@cwu.edu

March 13, 2017

Shelly Carow
Chief Grants Management Officer
Office of Grants Management
National Center for Complementary and Integrative Health
6707 Democracy Boulevard, Suite 401
Bethesda, MD 20892-5475

Dear Dr. Carow,

This letter is to serve as the final report of a non-compliance event at Central Washington University (Assurance no. A4729-01).

On October 5, 2016, graduate student **Secondary Individual** met with Dr. Jason Irwin, IACUC Chair, at her request, to discuss animal use in the laboratory of Dr. Blaise Dondji. **Secondary Individual** was a research assistant funded by NIH grant 1R15AT008546-01 (held by **Room #** and **Secondary Individual**). Her concern was the large number of animals being used and whether the number of animals approved by the IACUC (CWU protocol no. A081401) had been exceeded. Upon request, she provided Dr. Irwin with written documentation on the number of animals that had been used for the project to date ("Hamster Inventory"). Careful review of the document indicated that 661 hamsters had been euthanized to as of 10/21/2016 while the approved protocol stated that 365 would be used. A revision to the protocol, which had not yet been approved, increased the request to 500 animals.

The IACUC met at 3:30pm on Oct. 21st and voted to temporarily suspend Dr. Dondji's protocol associated with the NIH project. The IACUC met with Dr. Dondji on 10/25/16 to gather more information. At that meeting, Dr. Dondji took responsibility for the overage. The IACUC was satisfied that the overage was based on negligence/lack of oversight, not a deliberate action to exceed the number of approved animals. The preliminary report was submitted to OLAW (Dr. Brent Morse, Compliance Oversight) on 10/28/2017 and to the USDA (Dr. Robert Gibbens) on 11/1/2016.

In response to the non-compliance exhibited by Dr. Blaise Dondji with regards to animal use, the IACUC took the following actions:

1. Protocol A081401 was terminated by the IACUC on 10/27/2016. No further work was performed under this protocol.
2. Dr. Dondji submitted new protocols to (1) develop a breeding colony of hamsters to support future research (approved by the IACUC Jan. 27, 2017) and (2) allow maintenance of hookworms using infected hamsters (approved by the IACUC Jan. 31, 2017). Another protocol, specifically to support any further research related to NIH grant 1R15AT008546-01, has been reviewed by the IACUC and is currently being updated/edited by the Dr. Dondji.
3. In accordance with IACUC instructions, Dr. Dondji has changed the method by which he records the number of animals being used in his laboratory, including a list of the protocol number associated

Institutional Animal Care and Use Committee

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with each animal, maintenance of a running total of animals used for each protocol, and information on how the animals were used and their final disposition.

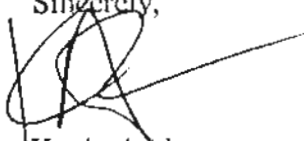
4. As requested by the IACUC, Dr. Dondji completed the "Mentoring" portion of the Responsible Conduct of Research training offered through the Office of Research Integrity, U.S. Department of Health and Human Services.

Changes to the Animal Care and Use Program:

5. CWU's new on-line protocol application system is in the final stages of development. This system will allow anyone (faculty, staff, or CWU student) the ability to view any protocol in which they are named as a participant. (The current system allows this only for the originator of a protocol and the faculty mentors of students that have submitted protocols.)
6. The IACUC has developed, with the input from researchers, a standard form to document/track animals moving through the animal care and use program. This record is being kept in a known location within the secure facilities where animals are housed. This will allow easier and more frequent checks of the number of animals being used and comparison of this value to the number approved (which is already posted in animal care areas).

Questions regarding the details of the history of ~~this event or the~~ corrective actions taken may be directed to Dr. Jason Irwin, IACUC Chair (irwinj@cwu.edu, Phone Number).

Sincerely,



Kevin Archer
Institutional Official and Dean,
Graduate Studies and Research

Institutional Animal Care and Use Committee

400 East University Way • Ellensburg, WA 98926-7510

E-mail: iacuc@cwu.edu • Web: www.cwu.edu/iacuc

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Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Wednesday, March 15, 2017 10:13 AM
To: 'Kevin Archer'; Carow, Shelley (NIH/NCCIH) [E]
Cc: [REDACTED] [REDACTED]
Subject: RE: Final OLAW Report Central Washington University

Thank you Dr. Archer. OLAW will send you a response to your report soon.

Regards, Brent Morse

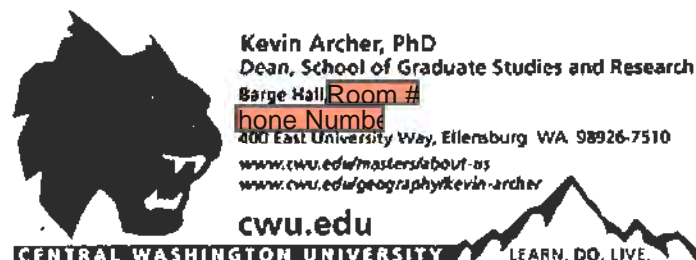
Brent C. Morse, DVM, DACLAM
 Animal Welfare Program Specialist
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

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From: Kevin Archer [mailto:Kevin.Archer@cwu.edu]
Sent: Tuesday, March 14, 2017 5:52 PM
To: Carow, Shelley (NIH/NCCIH) [E] <carows@mail.nih.gov>
Cc: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; [REDACTED]@cwu.edu; [REDACTED]
 [REDACTED]@cwu.edu
Subject: Final OLAW Report Central Washington University

Dear Shelly Carow:
 Please find attached the final report of a non-compliance event at Central Washington University (Assurance no. A 4729-01).

Sincerely,
 Kevin Archer
 Institutional Official



<http://www.cwu.edu/masters/>



A4729-A

October 24, 2016

Brent Morse, DVM
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

Dear Dr. Morse,

This letter is to serve as the initial report of a non-compliance event at Central Washington University (Assurance no. A4729-01).

On October 5, 2016, graduate student [redacted] met with me, at her request, to discuss animal use in the laboratory of Dr. Blaise Dondji. [redacted] is a research assistant funded by NIH grant 1R15AT008546-01 (held by [redacted] and Blaise Dondji) and works solely on this project. Her concern was the large number of animals being used and whether the number of animals approved by the IACUC had been exceeded. Upon request, she provided me with written documentation on the number of animals that had been used for the project to date ("Hamster Inventory"). Careful review of the document indicates that 661 hamsters have been euthanized to date (10/21/2016) while the approved protocol stated that 365 would be used. A revision to the protocol, which had not yet been approved, increased the request to 500 animals.

After meeting with [redacted] I investigated the situation further, largely to seek an alternative source of information regarding the number of animals used. My intent was to protect [redacted] anonymity as the reporter of this information. I took this action knowing that no additional animals were to be infected until 10/21/16, so the number of animals used would not increase until that date. (Note that 25 animals were euthanized on 10/18/16, but these were animals that had been infected on 9/24/16. Therefore, they had reached the experimental endpoint so needed to be euthanized before adverse symptoms developed.) I was unsuccessful in finding an alternate source for the information on animal use. On the morning of Oct. 21st, I sent an email and text messages to Dr. Dondji requesting that no additional animals be infected. At that point, [redacted] revealed to Dr. Dondji that she had provided evidence to me regarding the number of animals used by the laboratory. At 10:00am on Oct. 21st, I met with Dr. Dondji in the presence of [redacted] Department Chair, to discuss the number of animals used. Immediately after that meeting, I informed the IO, Dr. Kevin Archer, of the situation by telephone. The IACUC met at 3:30pm on Oct. 21st and voted to temporarily suspend Dr. Dondji's protocol associated with the NIH project. Dr. Dondji's keys to the animal facility (where his research animals are housed) were collected at 5:00pm the same day. Animal care was taken over by department staff as there were no infected animals at that time.

Institutional Animal Care and Use Committee

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10/25/2016 3:39PM (GMT-04:00)



The IACUC is meeting with Dr. Dondji early this week (10/25/16) before taking further action.

Sincerely,



Dr. Jason Irwin
IACUC Chair
Professor, Biological Sciences
Central Washington University
MS-7537, 400 E. University Way
Ellensburg, WA 98926
Ph. Phone Number
irwinj@cwu.edu

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10/25/2016 3:39PM (GMT-04:00)

**Department of Biological Sciences
Fax Cover Form**

CENTRAL WASHINGTON UNIVERSITY

Department of Biological Sciences
400 E. University Way
Ellensburg, WA 98926-7537
Phone: 509-963-2731
Fax: 509-963-2730

To: Dr. Brent Morse, OLAW
From: Jason Druil, IACUC Chair Date: 10/25/16
RE: Compliance

Please Number of pages to follow: 2

Comments:



Division of Compliance Oversight

Record of Call for Case # A4729-A

Date & Time	Message	Initials
3/1/17 12:55	left VM for Dr. Irwin requesting update & final report.	<i>BM</i>
3/2/17	He returned call, left VM & will call me back.	<i>BM</i>