

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

May 15, 2019

Re: Animal Welfare Assurance D19-01053 [OLAW Case A]

Dr. Geoffrey Klein Vice Provost for Research, Graduate Studies and Assessment Christopher Newport University 1 Avenue of the Arts Newport News, Virginia 23606

Dear Dr. Klein,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 6, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Christopher Newport University (CNU). Your letter supplements the prompt report to this office by you via email on January 14, 2019. According to the information supplied, OLAW understands that PHS-funded animal activities (R01NS102306-01) involving six mice took place in October 2017 without the University having an OLAW-approved Animal Welfare Assurance. This error was discovered in December 2018 and this grant-related work was halted until an Assurance could be obtained.

Corrective and preventive actions included CNU successfully obtaining an OLAW-approved Animal Welfare Assurance on May 3, 2019. In addition, any costs associated with the animal activity have been removed from the grant. Finally, the *Request for Laboratory Purchase* form has been updated to include the funding source and Animal Care Facility staff have been trained to review the source of the funds prior to animal purchase.

The prompt consideration of this matter by Christopher Newport University was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to resolve the issues and prevent recurrence were appropriate. We recognize that there were extenuating circumstances regarding this incident and we commend CNU for taking appropriate action to mitigate the noncompliance when discovered. We find no cause for further action by this office at this time.

Sincerely,

(b) (6)

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

cc: IACUC Contact

Tijuanna DeCoster, Chief Grants Management Officer, NINDS

D19-01053-A



May 6, 2019

Brent Morse, DVM
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

Dear Dr. Morse:

Christopher Newport University, in accordance with PHS Policy IV.F.3., provides this report of noncompliance regarding an incident related to the procurement, care, and use of mice to support work on a NIH Grant R01NS102306-01 without PHS Assurance. This incident was first reported to Dr. Brent Morse, OLAW, on January 14, 2019 via email from Dr. Geoffrey Klein, PhD, Vice Provost and IO at Christopher Newport University.

In late-December 2018, it was determined that Christopher Newport University (CNU) was in noncompliance with PHS Policy as it did not have Domestic Animal Welfare Assurance to conduct work associated with NIH Grant R01NS102306-01. Prior to this time, CNU was under the impression that an executed MOU between CNU and Emory-Prime Institution on this multi-PI R01 grant—was sufficient to move forward with grant-related activities. In addition, CNU had not received a request to negotiate a PHS Assurance from OLAW upon receipt of the grant. Therefore, on September 27, 2017, after funds had been issued as a sub-award from Emory University to CNU, our principal investigator ordered six C57BL/6 male mice from Charles River Laboratories, resulting in the use of \$218.73 from the direct costs of the award. The mice arrived at CNU on October 4, 2017 and were housed in CNU's Animal Care Facility until October 9, 2017. As described in the approved IACUC protocol, mice were allowed to acclimate for a minimum of 3 days, and then they were euthanized in the form of a non-survival surgery (transcardial perfusion under deep anesthetization) in order to obtain brain tissue. It was the submission of an IACUC protocol renewal by our PI in December 2018 that triggered a reinvestigation of the original MOU and consultation with Emory. Emory followed up with the NIH Grants Manager and OLAW to determine that PHS Assurance was needed to conduct this work. As soon as it was determined we were in noncompliance, CNU halted this grant-related work with vertebrates until Assurance could be obtained.

Christopher Newport University just completed its negotiation with OLAW for a Domestic Animal Welfare Assurance (Identification Number: D19-01053). With this Assurance, work will now recommence according to the grant and IACUC-approved protocol (2019-02) entitled, "Norepinephrine-dopamine interactions underlying arousal, learning and memory."

1 University Place Newport News, Virginia 23606-2949 Voice (757) 594-7000 TDD (757) 594-7938 FAX (757) 594-7713 A review of billing records showed that all direct costs associated with the procurement, care, and use of the mice during September – October of 2017 were initially paid from NIH Grant R01NS102306-01. These costs have been subsequently removed from this account and invoiced to and paid from a nonfederal source.

Finally, in an effort to enhance our animal procurement process, we have updated the *Request for Laboratory Purchase* form to include information regarding the nature of the funding source. Animal Care Facility staff have been trained in the use of the new procurement form to review source of funds prior to animal purchase.

Christopher Newport University is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Matthew Campolatarro, PhD, IACUC Chair.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Geoffrey Klein, PhD
Vice Provost for Research, Graduate Studies, and Assessment
Institutional Official
Christopher Newport University

Wolff, Axel (NIH/OD) [E]

From:	OLAW Division of Compliance Oversight (NII-	1/OD)		
Sent:	Tuesday, May 7, 2019 7:26 AM			
To:	Geoffrey Klein			
Cc:	OLAW Division of Compliance Oversight (NIF			
Subject:	RE: Final Report (Non-compliance) - Christop	her Newpor	t University	
Thank you for this report, Dr. Klei	n. We will send a response soon.			
Axel Wolff, M.S., D.V.M.				
Deputy Director, OLAW				
			**	
From: Geoffrey Klein < geoffrey.kl				
Sent: Monday, May 6, 2019 5:27				
•	Oversight (NIH/OD) <olawdco@od.nih.gov></olawdco@od.nih.gov>			
	Use Committee <iacuc@cnu.edu></iacuc@cnu.edu>			
Subject: Final Report (Non-compi	iance) - Christopher Newport University			
To Whom it May Concern,				
To whom it may concern,				
Please find the final report of a no	oncompliance issue at Christopher Newport L	Jniversity at	tached below.	. Please do not
hesitate to contact me if you have				
Geoffrey				
Coeffroy C. Klain Dh.D.				
Geoffrey C. Klein, Ph.D. Vice Provost				*
Associate Professor of Cher	nistry			
Christopher Newport University	,			0
1 Avenue of the Arts				
Newport News, VA 23606 Email: geoffrey.klein@cnu.edu				
Phone: (b) (6)				
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2				

Morse, Brent (NIH/OD) [E]

From:

Geoffrey Klein < geoffrey.klein@cnu.edu>

Sent:

Tuesday, January 22, 2019 4:16 PM

To:

OLAW Division of Compliance Oversight (NIH/OD)

Subject:

Re: Preliminary Report - Christopher Newport University

Thank you, Brent. Best,

Geoffrey Klein, PhD Vice Provost Associate Professor of Chemistry Christopher Newport University Sent from my iPhone

On Jan 22, 2019, at 3:28 PM, OLAW Division of Compliance Oversight (NIH/OD) < olawdco@od.nih.gov > wrote:

Thank you for your follow-up Dr. Klein. Sorry I missed your call. You can send your final report at any time. We will then send you an official response to your final report. After your Assurance is approved, the documents for the case will be filed under the University's Assurance number.

Sincerely, Brent Morse

Brent C. Morse, DVM, DACLAM
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.

From: Geoffrey Klein [mailto:geoffrey.klein@cnu.edu]

Sent: Tuesday, January 22, 2019 2:29 PM

To: OLAW Division of Compliance Oversight (NIH/OD) < olawdco@od.nih.gov >

Subject: Re: Preliminary Report - Christopher Newport University

Good afternoon,

This message is in response to an email sent by Brent Morse in regards to the recent CNU submission of a preliminary report of non-compliance. I have called and left a message, but thought it might be easiest to send a quick email. I did receive your call last week and will move forward with moving the expense for the animals from the NIH award to a non-federal source. In addition, Christopher Newport will work to implement the other action items articulated in the preliminary report to ensure this does not happen again.

My only question I have is associated with the timing of the submission of a final report. Should we wait to submit our final report until after our Assurance documentation has been reviewed

and approved? Or, can we submit a final report regardless of when PHS-Assurance has been obtained? Thanks in advance, Geoffrey On Tue, Jan 15, 2019 at 3:08 PM OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> wrote: Hello Dr. Klein, Thank you for submitting this report. We will open a compliance case file. I have left you a voicemail to give some guidance in how you should proceed. I am out of the office until Friday morning but you may call our central # (301-496-7163) if you need guidance before then. Otherwise, if I can be of assistance, do not hesitate to call me at 301-594-2921. 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: Geoffrey Klein [mailto:geoffrey.klein@cnu.edu]

Sent: Monday, January 14, 2019 1:20 PM

To: OLAW Division of Compliance Oversight (NIH/OD) < olawdco@od.nih.gov >

Cc: Institutional Animal Care and Use Committee < iacuc@cnu.edu >

Subject: Preliminary Report - Christopher Newport University

2

To Whom it May Concern,

Please find a preliminary report of a noncompliance issue at Christopher Newport University attached below. Christopher Newport University is in the final stages of submitting its application for Domestic Animal Welfare Assurance; therefore, does not currently have an Assurance number. Please do not hesitate to contact me if you have any questions. Best,

Geoffrey

Geoffrey C. Klein, Ph.D.
Vice Provost
Associate Professor of Chemistry
Christopher Newport University
1 Avenue of the Arts
Newport News, VA 23606
Email: geoffrey.klein@cnu.edu
Phone: (b) (6)



Geoffrey C. Klein, Ph.D.
Vice Provost
Associate Professor of Chemistry
Christopher Newport University
1 Avenue of the Arts
Newport News, VA 23606
Email: geoffrey.klein@cnu.edu
Phone: (b) (6)



Memorandum

To:

Division of Compliance Oversight, OLAW

From:

Geoffrey C. Klein, Vice Provost and IO

Subject:

Preliminary Report - Noncompliance

Date:

1/14/2019

(1) Name and Contact Information

Geoffrey C. Klein
Christopher Newport University
1 Avenue of the Arts
Newport News, VA 23606
email: geoffrey.klein@cnu.edu
Phone:

(b) (6)

(2) Name of Institution

Christopher Newport University

(3) Assurance Number

No Assurance Number

(4) Funding component and if contacted

Emory University (Prime) – Notified (1/3/2019) NIH (1R01NS102306-01) – Notified (1/14/19)

(5) Brief description of incident

On April 11, 2017, following submission of the grant that was funded officially on May 29, 2017 (original NOA), (b) (6) was contacted by (b) (6) (7) was requested. As described in the Email #1, copied below, Emory, being the prime institution on this Multi-PI RO1, stated that we did not need to provide IACUC approval, but to submit an MOU between institutions stating that (b) (6) had IACUC approval to perform vertebrate animal experiments. When specifically inquiring about the title of the MOU (Between Collaborating PHS-Assured Institutions), (b) (6) stated that CNU was not PHS-Assured, but did have USDA Assurance. To this,

(b) (6)

responded that that was fine and to have the form signed anyway. It was at this point that believed that she could continue work using C57BL/6 mice under this MOU. An IACUC protocol had been approved by CNU's IACUC for the preliminary work for this grant proposal (IACUC Tracking Number 2015-2). It was the understanding of Dr. believed and the IACUC at the time that if PHS Assurance was required, an invitation to apply for PHS Assurance would be issued by OLAW. In the original Statement of Work and Detailed Budget Justification, as well as the Revised Statement of Work and Revised Detailed Budget Justification (as the grant's final budget was cut by 16%), it was written that mice would be used by the NIH or OLAW to apply for Domestic Animal Welfare Assurance.

Therefore, on September 27, 2017, after funds had been issued as a sub-award from Emory University to CNU, (b) (6) ordered six C57BL/6 male mice from Charles River Laboratories, resulting in the use of \$218.73 from the Direct Costs of the award. The mice arrived to CNU on October 4, 2017 and were housed in CNU's Animal Care Facility until October 9, 2017. As described in the approved IACUC protocol, mice were allowed to acclimate for a minimum of 3 days (it was in actuality 5 days), and then they were euthanized in the form of a non-survival surgery (transcardial perfusion under deep anesthetization, performed by (b) (6) in order to obtain brain tissue for the proposed Experiments in Aim #1.

After submitted a new IACUC protocol to continue with the Aims of the study in December of 2018, CNU's IACUC revisited the MOU and at this time consulted with Emory University who then contacted the NIH Grants Manager for this grant (Olamide Adeniyi, NINDS) who then contacted OLAW (Kiara A. James). An email was then received by (b) (6) on January 3, 2019 to submit a new application for Domestic Animal Welfare Assurance to OLAW as soon as possible (N19 01053). (b) (6) contacted Emory to ask whether CNU needed to report the use of mice in 2017 prior to receiving Assurance and (b) (6) (6) was told to consult with OSP and the IACUC at CNU (Email #2 below).

(6) Plan and schedule for correction and prevention (if known)

Currently, Christopher Newport University plans to implement a three-pronged approach to correct and prevent a similar incident from occurring again in the future. (1) All grant work (NIH grant R01NS102306-01) with vertebrates has been stopped until Christopher Newport University receives PHS Assurance. (2) Christopher Newport University (CNU) has been asked to submit an application for Domestic Animal Welfare Assurance to OLAW and plans to submit this document by COB January 15, 2019. Work with live vertebrates on this grant will only begin when Christopher Newport has received PHS Assurance. (3) The Animal Care Facility will make changes to the "Request for Laboratory Purchase" form to include a question regarding nature of source (i.e. federal or non-federal). Animal Care Facility staff will be trained in the use of the new procurement form to review source of funds prior to animal purchase.

(7) Timeframe for final report from the Institutional Official

Christopher Newport plans to submit a final report to OLAW no later than 30 days from the submission of the preliminary report.

Email #1: JIT Information & MOU (04/11/2017):

REQUEST FOR JUST-IN-TIME INFORMATION FOR 1R01NS102306-01 -

EPEX 38822

(b) (6)

Apr 11, 2017, 10:53 AM

Hi (b) (6)

I work with (b) (6) and we need additional information for the JIT. Instead of sending us the IACUC approval, we are now required to have an Memorandum of Understanding between the Prime's Program of Animal Care and Use and the Sub-award's Program of Animal Care and Use.

I have attached the MOU. Please have a representative from your Animal Care and Use program complete this form, sign and return to me ASAP.

Best regards,

(b) (6)

(b) (6) to (b) (6)

Hi (b) (6)

I just was wondering what I should do since we do not have PHS Assurance yet (but we do have USDA), and it is our understanding that we cannot apply for PHS Assurance until someone at the university is awarded an NIH grant. How would you like me to proceed on that?

Additionally, since I am the chair of our IACUC, can the Vice Chair be the representative that signs the form or should our Institutional Official sign off on it?

Thanks (b) (6)

(b) (6)

Hi **(b) (6**)

Go ahead and have the Vice Chair sign. The language in the MOU seems to address the USDA, so if you have USDA, then this should be fine!

(b) (6)

(b) (6)
From:

Sent: Tuesday April 11 2017 11:15 AM

(b)

Subject: Re: REQUEST FOR JUST-IN-TIME INFORMATION FOR 1R01NS102306-01 - EPEX 38822

(b)(6)

Great, thank you

(b) (6)

(b) (6)

Hi(b) (6),
Please find attached the MOU for the JIT. Please let me know if I need to change anything. Thanks

(b) (6)

Thank you very, very much!
Best,
(b) (6)

Email #2: Advice Sought from Emory on Whether to Report this incident to OLAW (01/03/2019):

(b) (6)	Fri, Jan 4, 12:53 PM (8
to me, (b) (6)	days ago)
Hi (b) (6)	
Your inquiry is out of my area of expertise, so I forwarded it on to our OSP contact person. Her respensively your OSP and IACUC contacts on your message to me, so it sounds like any follow-from them.	
(b) (6)	
From: (b) (6) Date: Friday, January 4, 2019 at 12:40 PM To: '(b) (6) Subject: RE: Follow-up question: 1 R01 NS102306-01 Interinstitutional Assurance request (Award %3)	38822)
Hi (b) (6) I would advise to discuss with her OSP and IACUC office at CNU. Thank you,	
(b) (б)	
From: (b) (6) Sent: Friday, January 4, 2019 10:23 AM	
To: (b) (6) Cc:	(b) (6)
(b) (6) Subject: Follow-up question: 1 R01 NS102306-01 Interinstitutional Assurance request (Award %388)	22)
Hi (b) (6)	
Please see the second paragraph below in (b) (6) message, and advise on any steps taken.	hat should be
Thanks, (b) (6)	

				(b) (6)

Date: Thursday, January 3, 2019 at 5:52 PM

(b) (6) Institutional Animal Care and Use Committee < iacuc@cnu.edu>, Geoffrey To:

Klein <geoffrey.klein@cnu.edu> (b) (6)

Subject: Re: FW: 1 R01 NS102306-01 Interinstitutional Assurance request

Hi again (b) (6)

Cc:

I just received word from Geoffrey Klein that we should be able submit the Domestic Assurance Document in the next two weeks, or 10 business days. The sample document we were sent by OLAW is the one we have used to develop our draft domestic assurance, therefore they do not see any issues with our ability to finalize our submission in the given timeframe.

I have contacted IACUC about my new protocol under review. My IACUC and IO were wondering, however, if we need to report at some point to OLAW that in September of 2017 I did purchase 6 mice with this grant funding prior to the issue of PHS Assurance being raised. I personally was under the impression that since that purchase was made while Protocol 2015-2 (that was listed on our MOU, attached) was still active, that I was in congruence with animal regulations. Your opinion on how to handle this particular issue would be greatly appreciated.

Thanks again, (b) (6)

(b) (6)

Morse, Brent (NIH/OD) [E]

From:

OLAW Division of Compliance Oversight (NIH/OD)

Sent:

Tuesday, January 15, 2019 3:08 PM

To:

Geoffrey Klein; OLAW Division of Compliance Oversight (NIH/OD)

Cc:

(b) (6) Institutional Animal Care and Use Committee

Subject:

RE: Preliminary Report - Christopher Newport University

Hello Dr. Klein,

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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: Geoffrey Klein [mailto:geoffrey.klein@cnu.edu]

Sent: Monday, January 14, 2019 1:20 PM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc:

(b) (6) Institutional Animal Care

and Use Committee <iacuc@cnu.edu>

Subject: Preliminary Report - Christopher Newport University

To Whom it May Concern,

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Geoffrey

Geoffrey C. Klein, Ph.D. Vice Provost Associate Professor of Chemistry Christopher Newport University 1 Avenue of the Arts Newport News, VA 23606