



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) 480-3387

May 4, 2020

Re: Animal Welfare Assurance
#A3711-01 (OLAW Case T)

Dr. Brian Gladue.
Vice President for Research
University of North Texas
Health Science Center
3500 Camp Bowie Blvd. – EAD 858
Fort Worth, Texas 76107

Dear Dr. Gladue,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 23, 2020 letter reporting a noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at the University of North Texas Health Science Center. From the information provide, it is understood that in February 2020 it was determined that a pilot study using mice was performed without an approved animal care and use protocol. It was not stated if the animals were on a project funded by the PHS or NSF.

Corrective and preventive actions included suspension of the protocol until the following corrective action plan is completed: a letter detailing the incident and a corrective action plan within the PI's laboratory to ensure that such an oversight does not occur in the future; a new protocol must also be submitted to the IACUC for review and approval; a meeting with an IACUC subcommittee, the PI and all personnel listed on the protocol prior to the continuation of animal activities.

OLAW believes that the corrective measures by the University of North Texas Health Science Center are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals for institutional self-monitoring, self-correction, and self-reporting. If the activity was PHS funded, no charges should be made to the grant during the period of non-compliance. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C. Morse

-S

Date: 2020.05.04 20:10:41 -04'00'

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

cc: IACUC contact



Office of the Vice President for Research and Innovation

April 23, 2020

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 20892-7982

Dear Dr. Morse,

The University of North Texas Health Science Center, in accordance with Assurance D16-00417 (A3711-01) and PHS Policy IV.F.3., provides this report of noncompliance regarding an incident of protocol deviation.

Description of Reportable Incident:

In February 2020, during Research Appreciate Day abstract review it was discovered that a pilot study using mice was done without an approved protocol. The proof of concept study used C57BL/6 mice to determine whether reconstituted high-density lipoprotein can be used to deliver siRNAs to the brain. We believe that this infraction occurred due to a lack of communication between the PI and his staff, and prompted us to add a mandatory meeting between the PI, personnel and IACUC subcommittee to go over responsibilities within the corrective action plan.

On February 25 and March 24, 2020, the IACUC discussed the incident and agreed to the corrective actions:

1. A suspension of the protocols until the following requirements are completed
2. A letter detailing the incident, and a corrective action plan within the PI's laboratory to ensure that such an oversight does not occur in the future.
3. Re-training of the PI and staff on CITI
4. A new protocol submitted and approved.
5. A meeting with an IACUC subcommittee to discuss responsibilities with PI and personnel listed on the protocol

The University of North Texas Health Science Center 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 Nathalie Sumien, Ph.D., IACUC Chair at (b) (6)

Thank you for your consideration of this matter.

Sincerely, (b) (6)

Brian Gladue, PhD
 Vice President for Research and Innovation
 Institutional Official
 University of North Texas Health Science Center

Cc: Nathalie Sumien, PhD, IACUC Chairman
 Egeene Daniels, DVM, Director, Department of Laboratory Animal Medicine

(b) (6)
 Tania Ghani, MS, CIP, Director, Office of Research Compliance

Division of Research and Innovation
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Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, April 27, 2020 7:52 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of Noncompliance Regarding Protocol Deviation Incident

Thank you for this report, (b) (6) We will send a response soon.

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

From: (b) (6)
Sent: Friday, April 24, 2020 1:59 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Gladue, Brian <Brian.Gladue@unthsc.edu>; Sumien, Nathalie <Nathalie.Sumien@unthsc.edu>; (b) (6)
(b) (6) Daniels, Egeenee
<Egeenee.Daniels@unthsc.edu>
Subject: Report of Noncompliance Regarding Protocol Deviation Incident

Good Afternoon,

Please find attached a Report of Noncompliance Regarding Protocol Deviation Incident at the University of North Texas Health Science Center.

If you have any questions regarding this report, please contact:

Nathalie Sumien, PhD
IACUC Chair
Nathalie.Sumien@unthsc.edu

Thank you,

(b) (6)