



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

January 23, 2019

Re: Animal Welfare Assurance
A4365-01 [OLAW Case 3U]

Stephan S. Monroe, Ph.D.
Associate Director for Laboratory
Science and Safety
Centers for Disease Control
1600 Clifton Road NE, (b)(6)
Atlanta, GA 30333

Dear Dr. Monroe,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 14, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Centers for Disease Control and Prevention - Atlanta. According to the information provided, OLAW understands that during an AAALAC site visit in October 2018 it was identified that plasma was being collected from goats more frequently than that approved in the protocol. Review of animal health records by veterinarians did not reveal negative effects on the animals.

Corrective and preventive actions included re-training for all protocol associates and CMB veterinary staff regarding the importance of reviewing all procedures and their approved frequencies before starting animal work, and on ensuring that the protocol is followed. An amendment to the protocol was submitted to reflect that collection of 1000 ml of plasma during a two week period is permissible.

The prompt consideration of this matter by the Centers for Disease Control and Prevention was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to resolve the issue and prevent recurrence were appropriate. 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
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Chair



Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

PHS Assurance# A4365-01

January 14, 2019

Dr. Brent Morse
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, MD 20892-7982

Dear Dr. Morse,

During a site visit conducted October 15 – 18, 2018, site visitors from the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) conducted records review and identified a protocol noncompliance involving plasma collection from goats. CDC's Deputy Chief veterinarian was notified of the incident and the incident was investigated.

Upon careful review, CDC concurred with AAALAC's findings that the protocol was approved to collect up to 1000 ml of plasma every 30 days via plasmapheresis. However, plasmapheresis was being performed as often as every 48 hours, which was not in the IACUC-approved protocol or amendment.

CDC veterinarians also investigated to determine any potential negative impacts on animal welfare. They determined that clinical chemistry findings on the serial, minimal blood draws at the beginning of each plasmapheresis procedure clearly demonstrated that serial plasmapheresis did not have a significant negative impact on the clinical status of these animals. CDC veterinarians also reviewed the records of these animals and did not find any untoward effects on animal health.

In response to this incident, all protocol associates and CMB veterinary staff were re-trained on the importance of reviewing all procedures and their approved frequencies in the protocol before starting animal work, and on the importance of ensuring that the protocol is followed. An amendment to the protocol was also submitted with annual review to reflect that permissible collection volumes of plasma via plasmapheresis is 1000 ml during a two week period.

The CDC-Atlanta IACUC discussed this incident at the November 5, 2018 and December 7, 2018 meetings. The committee voted to report this incident to OLAW. Upon implementation of the corrective actions outlined above, the committee did not feel that any other actions were needed at this time.

Sincerely,

(b)(6)

1/14/2019

X *Stephan S. Monroe*

Stephan S. Monroe, PhD
Institutional Official
Signed by: PIV

Stephan S. Monroe, PhD
Institutional Official
Director, Office of Laboratory Science and Safety

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, January 14, 2019 2:33 PM
To: (b)(6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6)
(b)(6) Maines, Taronna (b)(6)
(b)(6)
Subject: RE: incident report submission for CDC-ATL (PHS Assurance# A4365-01)
Follow Up Flag: Follow up
Flag Status: Flagged

Thank you for submitting this report (b)(6) We will send an official response soon.

Best regards, Brent Morse

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

From: (b)(6)
Sent: Monday, January 14, 2019 2:16 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6)
(b)(6) Maines, Taronna (b)(6)
(b)(6)
Subject: incident report submission for CDC-ATL (PHS Assurance# A4365-01)

Dear Dr. Morse and colleagues,
Please find attached an incident report for submission.

Thank you,

(b)(6)

Centers for Disease Control and Prevention
1600 Clifton Road NE, (b)(6) Atlanta, GA 30333
(b)(6)
Telework Tuesdays, Fridays