



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

December 17, 2018

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

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 December 11, 2018 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. That letter updated a previous report to this office on October 10, 2018. According to the information provided, OLAW understands that during an audit of CDC-funded international animal work it was determined that five field studies with the University of Pretoria, South Africa involving animals had not undergone review by CDC's IACUC. Funds were immediately restricted for these activities. It was subsequently determined that all five studies had been completed.

Corrective and preventive actions included additional training for CDC's Center for Global Health headquarters and country offices. They have also been informed that all future animal study proposals must be reviewed and approved by the CDC-Atlanta IACUC in addition to the foreign entity's IACUC before any animal work may begin.

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**

December 11, 2018

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,

This letter is in follow-up to our previous report to OLAW on October 10, 2018 of a potential noncompliance with Public Health Service (PHS) Policy and suspension of animal work at the University of Pretoria in South Africa. The Centers for Disease Control and Prevention (CDC) Institutional Animal Care and Use Committee (IACUC) in Atlanta reviewed the protocols for all CDC extramurally-funded field studies involving animals at the University of Pretoria, South Africa at the full committee meeting held on November 5, 2018. The IACUC determined that there were five completed animal studies that were conducted in South Africa by the University of Pretoria using CDC funds that had not been reviewed and approved by the CDC IACUC.

As previously stated, the University of Pretoria has a foreign assurance with OLAW and all protocols were reviewed by the local foreign equivalent of an IACUC. However, because these protocols had only been reviewed and approved by the foreign equivalent (the University of Pretoria's IACUC) and had not been reviewed and approved by the CDC IACUC, per OLAW policy (under Frequently Asked Questions D.13), this represented a noncompliance with PHS Policy.

As stated, all five animal studies are completed. Therefore, we have taken the following corrective actions: CDC's Center for Global Health headquarters and country offices have received additional training and have been informed by the CDC Animal Care and Use Program Office (ACUPO) that all future animal study protocols must be reviewed and approved by the CDC-Atlanta IACUC in addition to the foreign entity's IACUC before any animal work may begin.

At the full committee meeting on November 5, 2018, the CDC-Atlanta IACUC voted to provide this follow-up report to OLAW. Upon taking the corrective actions outlined above, the committee did not feel that any additional measures were needed at this time.

Sincerely,

(b)(6)

12/11/2018

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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, December 13, 2018 7:39 AM
To: (b)(6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Follow-up incident report submission for CDC-ATL (PHS Assurance# A4365-01)

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

From: (b)(6)
Sent: Wednesday, December 12, 2018 3:51 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: Follow-up incident report submission for CDC-ATL (PHS Assurance# A4365-01)

Dear Dr. Morse and colleagues,
Please find attached a follow-up 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

Morse, Brent (NIH/OD) [E]

From: (b)(6)
Sent: Monday, October 29, 2018 10:20 AM
To: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: suspension of animal activity_A4365-01

Agreed. Will do.

(b)(6)

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

(b)(6)

Telework Tuesdays, Fridays

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Monday, October 22, 2018 2:34 PM
To: (b)(6)
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: suspension of animal activity_A4365-01

Hello (b)(6)

After further review I would like to delay responding to your October 10th letter until after your IACUC meets on November 5th in case there is any noncompliance found during their review of this issue. Please let me know if this is not agreeable with you. Otherwise, please send me an email after the IACUC meets to let me know if I should hold this open or if I can then just respond to the Oct 10th letter. Thanks.

All the best, Brent

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: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, October 11, 2018 10:20 AM
To: (b)(6) OLAW Division of Compliance Oversight (NIH/OD)
<olawdco@od.nih.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS) (b)(6)
(b)(6)
Subject: RE: suspension of animal activity_A4365-01

Morse, Brent (NIH/OD) [E]

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All the best, Brent

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

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Cc: Monroe, Steve (CDC/DDPHSS/OLSS) (b)(6)
(b)(6)
Subject: RE: suspension of animal activity_A4365-01

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

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: (b)(6)
Sent: Wednesday, October 10, 2018 5:17 PM



PHS Assurance# A4365-01

October 10, 2018

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,

In a recent audit of international animal work, CDC's Global Health program became aware of six CDC extramurally-funded field studies involving animals with the University of Pretoria, South Africa that had not undergone review by CDC's Institutional Animal Care and Use Committee (IACUC). The program immediately informed the Animal Care and Use Program Office (ACUPO) of this incident and restricted funds to the University of Pretoria, South Africa for these specific activities. In follow-up with the program, ACUPO determined that the University of Pretoria has a foreign assurance with OLAW and all protocols were reviewed by the local foreign equivalent of an IACUC. However, because these protocols had only been reviewed and approved by the foreign entity's IACUC (University of Pretoria's IACUC) and had not been reviewed and approved by the domestic institution's IACUC (CDC's IACUC), per OLAW policy under Frequently Asked Questions D.13, this represented potential noncompliance with Public Health Assurance (PHS) Policy.

The initial audit was performed by the CDC Global Health program as a follow-up to an incident that occurred in Bangladesh on May 7, 2018 and was reported to OLAW on July 11, 2018. The audit was one of a number of corrective action measures taken to ensure that all off-site international animal work was being appropriately reviewed and approved, and was in compliance with PHS Policy. The IACUC was informed of the existence of extramurally-funded field studies involving animals with the University of Pretoria, South Africa at the full committee meeting that took place on October 1, 2018. At that time, the IACUC voted to temporarily suspend all animal work funded by CDC at this specific institution until the CDC IACUC had reviewed all protocols involving animal use. In addition, prompt notification to OLAW was advised.

The IACUC will review the protocols, then discuss the findings of that review at the next full committee meeting scheduled for November 5, 2018. At that time the IACUC will promptly inform the Institutional Official of any noncompliances found, report noncompliances to OLAW as appropriate, and determine if the temporary suspension should be lifted or maintained.

Sincerely,

10/10/2018

(b)(6)


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

13. If an animal activity will be performed outside of the US (either by a foreign awardee or by a foreign institution as a subproject for a domestic awardee), is the awardees IACUC required to review and approve that activity?

When the awardee is a domestic institution (i.e., domestic award with a foreign component), PHS animal welfare requirements are applicable. Accordingly, the awardee remains responsible for animal activity conducted at a foreign site and must provide verification of IACUC approval. That approval certifies that the activity, as conducted at the foreign performance site, is acceptable to the awardee. The awardee IACUC may accept, as its own, the approval of a foreign entity's IACUC; however, the awardee IACUC remains responsible for the review. Additionally, the foreign institution must complete the Animal Welfare Assurance for Foreign Institutions (Foreign Assurance (<https://olaw.nih.gov/resources/documents/foreign.htm>)) available from OLAW. This document certifies that the institution will comply with the applicable laws, regulations, and policies of the jurisdiction in which the research will be conducted, and that the institution will be guided by the International Guiding Principles for Biomedical Research Involving Animals (https://olaw.nih.gov/sites/default/files/Guiding_Principles_2012.pdf) (PDF). OLAW encourages, but does not require, foreign institutions to use the standards in the *Guide* (http://www.nap.edu/catalog.php?record_id=12910)  (<https://grants.nih.gov/grants/disclaimer.htm>). If the prime awardee is a foreign institution, IACUC approval is not required.

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, October 11, 2018 10:20 AM
To: (b)(6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Monroe, Steve (CDC/DDPHSS/OLSS); (b)(6)
(b)(6)
Subject: RE: suspension of animal activity_A4365-01

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

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
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Office of Laboratory Animal Welfare
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To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Monroe, Steve (CDC/DDPHSS/OLSS) (b)(6)

(b)(6)

Subject: suspension of animal activity_A4365-01

Dear Dr. Morse and colleagues,
Please find attached a report of a suspension of an animal activity in South Africa.

Thank you,

(b)(6)

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

(b)(6)

Telework Tuesdays, Fridays