



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 6, 2019

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

Stephan S. Monroe, Ph.D  
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 May 3, 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 (CDC). According to the information provided, OLAW understands that the CDC Institutional Animal Care and Use Committee (IACUC) failed to review a field study conducted in the country of Georgia in collaboration with the Ministry of Agriculture (MOA). The initial Notice of Grant Award did not indicate that IACUC approval was required and 115 samples were collected from livestock without approval.

The immediate action taken upon discovery consisted of restricting funds to MOA and stopping the work until IACUC approval is obtained. The CDC Global Health program is conducting ongoing audits to ensure that all foreign collaborations receive initial review and approval by the CDC IACUC. A standard operating procedure (SOP) was developed to outline the actions that need to be taken before starting animal activities in a foreign country, including obtaining IACUC approval.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by CDC to comply with the PHS Policy. Also, please add to the SOP, if not already included, the requirement for a Foreign Assurance issued by this Office for any foreign collaborating site <https://grants.nih.gov/grants/olaw/assurance/500index.htm>. Thank you for informing OLAW about this matter.

Sincerely,

Axel Wolff, M.S., D.V.M.  
Deputy Director  
Office of Laboratory Animal Welfare

cc: IACUC Chair  
Chief, Animal Care and Use Program Office



PHS Assurance# A4365-01

May 3, 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,

In a recent end of year audit of international cooperative agreements involving animals, CDC's Global Health program became aware of a CDC extramurally-funded field study involving animals with the Ministry of Agriculture (MOA) in the country of Georgia 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 MOA, Georgia for these specific activities. In review of the Notice of Award (NOA) guidance documents that were sent to Georgia MOA, CDC's Global Health program determined that while year 2's NOA provided guidance to the MOA partner that IACUC approval is required before CDC funds can be released, year 1's NOA did not include these IACUC requirements. As a result, the MOA was not fully aware of the IACUC requirements and had used CDC approved carryover funds from year 1 to perform work on the study in December 2018 without IACUC approval. In total, 115 samples from livestock were collected. Although this was unintentional and was a routine disease surveillance activity by the MOA, conducting CDC funded animal work without IACUC approval represents a noncompliance with PHS Policy.

This end of year audit was a follow-up measure to two incidents in Bangladesh and South Africa that were reported to OLAW in 2018. In addition to the extensive number of corrective actions that were implemented in 2018 (and outlined in the two letters to OLAW in 2018), CDC's Global Health program is continuing to perform regular audits of international work involving animals throughout the year as well as end of the year audits prior to the next year's funding of projects to ensure that all off-site international animal work is being appropriately reviewed and approved, and is in compliance with PHS Policy. The Animal Care and Use Program Office is also writing a standard operating procedure outlining a step-by-step process for project determination and IACUC approval before animal work may begin and will require all country offices to acknowledge and sign that they have reviewed and understand the procedures. As stated, work on this study in Georgia has already ceased until CDC IACUC approval is obtained.

The IACUC discussed this incident and corrective actions at the March 4 and April 8, 2019 meetings and voted to report this noncompliance 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)

5/3/2019

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

**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, May 6, 2019 6:38 AM  
**To:** (b)(6)  
**Subject:** RE: incident report submission for CDC-ATL (PHS Assurance# A4365-01)

Thank you for this report, (b)(6) We will respond soon.

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

**From:** (b)(6)  
**Sent:** Friday, May 3, 2019 4:16 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6)  
(b)(6) 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)

(b)(6)

Centers for Disease Control and Prevention  
1600 Clifton Road NE, (b)(6) Atlanta, GA 30329  
(b)(6)

*Telework Tuesdays, Fridays*