



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
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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  
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May 6, 2021

Re: Animal Welfare Assurance  
A3822-01 [OLAW Case Q]

Dr. Robert Butera  
Vice President for Research and Development Operations  
Georgia Institute of Technology  
926 Dalney Street NW  
Atlanta, GA 30332-0415

Dear Dr. Butera,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 16, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Georgia Institute of Technology. According to the information provided, OLAW understands that during a 3-year review of a protocol, it was identified that the collaborator's OLAW Foreign Assurance had expired at which time Georgia Tech instructed the collaborator to immediately stop animal work. The study was PHS funded.

As a corrective measure, the Georgia Tech grant system was audited for Domestic and Foreign active awards involving live vertebrate animals including sub-awards to collaborating institutions and all institutions were in compliance other than the grant subject to this investigation and noncompliance. As a result of the investigation, the process for documenting and managing activities involving external institutions was revised to collect external institutions' assurance numbers and expiration dates which links to the Office of Sponsored Programs Award system to ensure tracking. Data from the experiments conducted by the collaborator past the expiration of the OLAW Assurance have not been published. Additionally, charges for the activities have been identified and Georgia Tech is working with the NIH funding component to remove charges from the award. Finally, the Foreign Collaborator has submitted a request for Assurance renewal to OLAW which is pending review.

OLAW appreciates the prompt consideration of this matter by Georgia Institute of Technology which is consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate steps have been taken to investigate this incident and to attempt to prevent recurrence. Please note for future reporting to OLAW that per PHS policy, section IV.F.3, "The IACUC, through the Institutional Official, shall promptly provide OLAW.." and inclusive of the Institutional Official's signature. We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,

Nicole L. Lukovsky-  
akhsanov -S

Digitally signed by Nicole  
L. Lukovsky-akhsanov -S  
Date: 2021.05.06 17:09:29  
-04'00'

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC contact  
Anna Taylor, Ph.D., NINDS  
Russell Blaisdell, NINDS

February 16, 2021

Animal Welfare Assurance D16-00474 (A3822-01)

Nicole Lukovsky-Akhsanov  
Division of Assurances  
Office of Laboratory Animal Welfare, NIH  
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Bethesda, Maryland 20892-6910

Phone: 301-480-8196  
Email: [Nicole.Lukovsky@NIH.gov](mailto:Nicole.Lukovsky@NIH.gov)

Dear Ms. Lukovsky-Akhsanov,

The Georgia Institute of Technology (hereafter Georgia Tech), in accordance with Assurance DD16-00474 [A3822-01] and PHS Policy IV.F.3., provides this report of noncompliance in follow-up to our phone call with Ms. Lukovsky-Akhsanov.

Per our prior communications, during the *de novo* review of Georgia Tech IACUC protocol A100186, it came to our attention that a collaborator's OLAW Foreign Assurance may have expired. Subsequent correspondence confirmed that no other relevant Assurance covered animal use, at which time Georgia Tech instructed the collaborator to immediately stop animal work. Below we have provided a summary of the activity, investigation, audit, corrective actions taken and mitigating factors.

Background:

In 2017, Georgia Tech received an award from National Institute of Health (NIH) for grant proposal R01NS100928 entitled "Neural mechanisms of locomotion evoked by epidural stimulation of the spinal cord." This grant includes research activities to be performed at Georgia Tech in collaboration with three sub-awardees. Activities involving the use of live vertebrate animals requiring active OLAW Assurances were performed at Georgia Tech and Pavlov Institute of Physiology (hereafter Pavlov).

Georgia Institute of Technology	DD16-00474 [A3822-01]
Pavlov Institute of Physiology, Russia	[A5952-01]

Prior to the abovementioned protocol renewal review, our office was under the impression that Pavlov was covered by an active Domestic Assurance through Monell Chemical Senses Center (D16-00083 (A3135-01)), as was described in the Vertebrate Animal Section (VAS) of the grant proposal. During the *de novo* review process, we questioned our Principal Investigator (PI) about the reference to the Monell Assurance, since they did not appear to be involved in the collaborative NIH grant. Through discussion with our PI and the Pavlov collaborator, we came to understand that Monell previously collaborated with Pavlov on an unrelated project. The Monell Assurance was included in the VAS section of NIH grant R01NS100928 in error by Pavlov. This dialogue identified that Pavlov had their own Foreign Assurance (A5952-01) at the time the grant was awarded, but that it had since expired.

Further correspondence with Pavlov regarding ongoing activities in connection with the NIH grant, identified that research involving vertebrate animals, approved by Pavlov IACUC (Protocol #01a/2017) continued beyond the expiration of their Foreign Assurance in March 2018.

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*A Unit of the University System of Georgia. An Equal Education and Employment Opportunity Institution.*

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#### Duration of activities:

Pavlov reviewed and determined that they conducted acute animal experiments on approximately 30 separate days after the expiration of their OLAW Foreign Assurance. Data from those experiments have not been published.

In collaboration with the Georgia Tech Office of Sponsored Programs (OSP), Georgia Tech and Pavlov PIs, we have identified the charges for activities conducted during the period when Pavlov did not have a valid Assurance. Georgia Tech is working with NIH to remove those charges from the award.

#### Assurance Renewal:

During our correspondence with Pavlov, we found that Pavlov misunderstood the Foreign Assurance process and request OLAW to take this into consideration as a mitigating factor.

OLAW's guidance document regarding Assurances (<https://olaw.nih.gov/guidance/obtaining-an-assurance.htm>) includes the following points:

#### Process of Obtaining an Assurance

- The PHS funding component notifies the institution of a pending grant or contract award (Notice of Award).
- If the awardee institution does not already have an Assurance, the funding component notifies OLAW that an Assurance is required.
- **OLAW contacts the institution to negotiate an Assurance. Note: OLAW does not accept or process unsolicited applications.**
- The institution prepares an Assurance document and submits it to OLAW.
- OLAW negotiates with the institution until the Assurance document meets the standards of the PHS Policy. Note: the institution may propose a program that exceeds the standards of the PHS Policy. After OLAW approves the Assurance document, the institution will be required to meet the standards they have proposed.

#### Assurance Renewal

The process for renewing an Assurance is similar to the process of obtaining a new Assurance. **Your institution will receive a reminder letter prior to the expiration date with instructions for submitting a renewal.** Note: Assurances will be renewed only if the institution continues to receive PHS funds, either directly or indirectly. OLAW requests institutions to submit the Domestic Assurance renewal document 4 months prior to the expiration date to allow time for review. It is important to submit the renewal documents promptly because the institution may not accept funds for animal activities unless the institution has a valid Assurance on file with OLAW (PHS Policy, section V.B.).

Given the above referenced guidance, Pavlov claimed to have been under the impression that they did not need to renew their assurance because they had not received the referenced reminder letter and OLAW will not accept unsolicited applications.

Once the assurance expiration was discovered, Georgia Tech requested that Pavlov begin drafting an Assurance renewal. As noted above, once it was clear that there was no other relevant Assurance covering the Pavlov animal activities, Georgia Tech asked Pavlov to immediately stop animal work. Pavlov has since submitted an Assurance renewal to OLAW (pending review).

#### IACUC Approval:

The research activity involving vertebrate animals at Pavlov was conducted under an IACUC-reviewed and -approved protocol, without lapse in approval, throughout the award period. Further, Pavlov's leadership certified to Georgia Tech that "animal research in Dr. Musienko's laboratory on NIH grant R01NS100928...[was] conducted in accordance with the NIH Guidelines of Laboratory Animal Care and Use (National Institutes of Health Publication No. 86-23, revised 1985) and the European Community Council Directive (24 November 1986, 86/609/EEC)."

Audit of all OLAW covered activities:

This event identified an area for program improvement at Georgia Tech. To address the issue identified, we audited the Georgia Tech grants system for active awards issued by Sponsors applicable to OLAW (PHS, HHS, NSF or NASA) that include sub-awards to collaborating institutions. From this audit, we identified grants that include sub-awards to foreign institutions, a subset of which involved live vertebrate animal work at the sub-awardee institution. Each award was reviewed to ensure all activities are covered by an approved IACUC protocol at an OLAW-assured institution. All awards were in compliance (other than the grant that is the subject of this investigation).

After auditing sub-awards to foreign institutions, we extended the audit to include sub-awards to domestic institutions involving live vertebrate animal activities at the sub-awardee institution. All active, ongoing, sub-awards are covered by an approved IACUC protocol at an OLAW-assured institution. New pending sub-awards, are in the process of being reviewed by an IACUC at an OLAW-assured institution.

Both audits concluded that all awards are in compliance (excluding the award subject of this investigation).

Program Improvement:

As a result of the subject investigation, the Georgia Tech IACUC office revised the procedure for documenting and managing activities involving external institutions. The IACUC office utilizes an electronic management system, TOPAZ Elements, for protocol submission, review and documentation. The Off-Campus Protocol application has been modified to collect external institutions' assurance number and expiration dates. The Off-Campus Protocol application directly links to the Office of Sponsored Award system to ensure compliance tracking.

Georgia Tech 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 do not hesitate to contact me directly.

Sincerely,

DocuSigned by:  
(b) (6)

153D08BCCC3E4C1  
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