



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

October 1, 2019

Re: Animal Welfare Assurance  
A3414-01 [OLAW Case U]

Dr. Frank Calzonetti  
The University of Toledo  
Vice President for Research  
3000 Arlington Avenue- CCE 2102  
Toledo, OH 43614

Dear Dr. Calzonetti,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 23, 2019 letter reporting the suspension of a PHS funded animal activity at the University of Toledo.

According to the information provided, OLAW understands that the activity was a breeding protocol and on September 10, 2019 the Department of Laboratory Animal Resources reported that the laboratory was not reporting animal numbers. Because this was the second serious non-compliance for this laboratory in the last six months the Institutional Animal Care and Use Committee (IACUC) voted to suspend the protocol until the laboratory arranged for personnel to conduct dedicated colony management. Based on its assessment of this explanation, OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy. Note that suspensions of animal activities on PHS-supported studies must be reported to the funding component. In addition, please notify this Office if or when the protocol is re-instated, and for future reports please provide the species of animal and the date of suspension. Thank you for keeping OLAW apprised on this matter.

Sincerely;

(b) (6)

Nicolette Petervary, VMD, DACAW  
Veterinary Medical Officer  
Office of Laboratory Animal Welfare

cc: IACUC Contact



**OFFICE of RESEARCH AND  
SPONSORED PROGRAMS**

THE UNIVERSITY OF TOLEDO

September 23, 2019

Axel Wolff, D.V.M.  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare National Institutes of Health  
Rockledge 1, Suite 360  
6705 Rockledge Drive  
Bethesda, MD 20892

Dear Dr Wolff:

In accordance with Assurance A3414-01 and PHS Policy IV.F.3., The University of Toledo (UToledo) provides this report of continuing noncompliance, reported to the IACUC on September 18, 2019.

On September 10, 2019, the Department of Laboratory Animal Resources (DLAR) reported to the IACUC that animal numbers were not being reported by a laboratory for a breeding protocol. This was the second serious non-compliance related to breeding reported to the IACUC in the last six months for this laboratory that the committee needed to address. Therefore, the IACUC voted to suspend the protocol until a formal arrangement was made for dedicated breeding colony management. The laboratory was given the option of hiring a Laboratory Technician or Manager to run the breeding colony or hiring DLAR to manage breeding colony operations. Until this is accomplished, the breeding protocol remains suspended.

NIH funds were used on this project.

UToledo is committed to protecting the welfare of animals used in research. Should you have any questions regarding this report, please contact Kathryn Eisenmann, Ph.D., IACUC Chair ([Kathryn.Eisenmann@utoledo.edu](mailto:Kathryn.Eisenmann@utoledo.edu)).

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Frank J. Calzonetti, PhD  
Vice President for Research  
Institutional Official

FRANK J. CALZONETTI, PH.D.

Vice President for Research

The University of Toledo, 2801 W. Bancroft St., MS 218, Toledo, OH 43606

PH: 419-530-4749; Email: [frank.calzonetti@utoledo.edu](mailto:frank.calzonetti@utoledo.edu)

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, September 27, 2019 6:44 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Non-Compliance and Suspension - Assurance A-3414-01

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

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**From:** (b) (6)  
**Sent:** Thursday, September 26, 2019 1:48 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** neelakanta.ravindranatha@nih.gov; Eisenmann, Kathryn M. <Kathryn.Eisenmann@utoledo.edu>; Calzonetti, Frank <frank.calzonetti@utoledo.edu>  
**Subject:** Non-Compliance and Suspension - Assurance A-3414-01

To Whom It May Concern:

Attached is a letter describing an incident of serious non-compliance that resulted in protocol suspension. It relates to NIH grant number 5R01HD081792. If you have any questions, please feel free to contact us.

Thank you,  
(b) (6)



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

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**From:** Wolff, Axel (NIH/OD) [E]  
**Sent:** Wednesday, October 2, 2019 12:15 PM  
**To:** Alsol, Hazel (NIH/NICHD) [E]  
**Subject:** FW: OLAW Case A3414-U  
**Attachments:** 0480\_001.pdf

**Subject:** OLAW Case A3414-U

Hello Ms. Tignor,

Attached please find (b) (6) final response to OLAW Case A3414-U and the relevant notices regarding charging to a grant during a suspension: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-044.html> , <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-081.html> . Yes, you should place a restriction on the notice of award and only allow expenses for maintenance and housing (this decision actually rests with the funding component but is commonly used during suspensions).

You could use the term "pending IACUC approvals" because the actual animal work cannot begin until there is IACUC approval or re-approval. Once this is received, the grant can once again be charged for animal research activities.

Let me know if you have any other questions.

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

**Morse, Brent (NIH/OD) [E]**

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**From:** Morgan, Eileen (NIH/OD) [E]  
**Sent:** Monday, September 30, 2019 3:52 PM  
**To:** Morse, Brent (NIH/OD) [E]  
**Subject:** FW: 5R01HD081792-Non-Compliance and Suspension - Assurance A-3414-01  
**Attachments:** Suspension September 2019.pdf

Brent,  
It seems this should be forwarded to Compliance Oversight, not the Division of Assurances.

Eileen

Eileen Morgan  
Director, Division of Assurances  
Office of Laboratory Animal Welfare, NIH  
6700B Rockledge Drive, Suite 2500, MSC-6910  
Bethesda, Maryland 20892-6910  
Phone (b) (6)

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**From:** OLAW Division of Assurances (NIH/OD)  
**Sent:** Monday, September 30, 2019 2:50 PM  
**To:** Morgan, Eileen (NIH/OD) [E] <morgane@od.nih.gov>  
**Cc:** Carrasco, T. Maritza (NIH/OD) [E] <carrascot@od.nih.gov>  
**Subject:** FW: 5R01HD081792-Non-Compliance and Suspension - Assurance A-3414-01

Hi Eileen,

I just find this email in the DOA Box, see below email. Are they allow to receive a restriction? I was off Friday.

Thank you,

*T. Maritza Carrasco*

Program Analyst | Division of Assurances, Office of Laboratory Animal Welfare, NIH, 6700B Rockledge Drive, Suite 2500, MSC 6910, Bethesda, MD 20892-6910 | Phone: (b) (6) | E-Fax: 301-451-5672 | carrascot@mail.nih.gov

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**From:** Alsol, Hazel (NIH/NICHD) [E] <hazel.alsol@nih.gov>  
**Sent:** Friday, September 27, 2019 10:11 AM  
**To:** Machado, Susann (NIH/OD) [E] <MachadoS@od6100m1.od.nih.gov>  
**Cc:** Ravindranath, Neelakanta (NIH/NICHD) [E] <neelakanta.ravindranath@nih.gov>  
**Subject:** 5R01HD081792-Non-Compliance and Suspension - Assurance A-3414-01

Hi Susann,

We have just received an email message from the Division of Compliance Oversight regarding suspension of IACUC approval due to serious non-compliance issue relating to NIH grant number 5R01HD081792. I've attached the suspension letter here.

We would like to get some guidance about this situation. It appears that a restriction on the notice of award should be placed restricting all activities and expenditures involving animal research and permitting only expenses for animal housing and maintenance.

We have a standard term for "pending IACUC approvals." Are there additional or perhaps other terms that should be placed on the notice of award, steps that should be taken?

We will also reach out to the institution regarding any charges related to animal research since the suspension.

I appreciate any guidance on this issue.

Sincerely,  
Hazel

**Hazel Cruz Tignor | Grants Management Specialist**

Grants Management Branch

*Eunice Kennedy Shriver* National Institute of Child Health and Human Development  
National Institutes of Health

6710B Rockledge Drive, MSC 7004, (b) (4) Bethesda, MD 20817

Phone: (b) (6) | Email: [hazel.alsol@nih.gov](mailto:hazel.alsol@nih.gov)



*Eunice Kennedy Shriver* National Institute  
of Child Health and Human Development

