



**Stop Animal Exploitation NOW!**

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Via Email: chamelli.jhappan@nih.gov ;  
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Dr. Francis Collins, Director, 5/19/18  
Office of the Director,  
National Institutes of Health,  
9000 Rockville Pike  
Bethesda, Maryland 20892  
Via Email: francis.collins@nih.gov

Ms. Jhappan, Dr. Collins,

I am writing to you today relevant to a project which is funded at the Indiana University School of Medicine. The project in question is #4R01CA155086, which is discussed in the attached documentation.

As you both know, the National Institutes of Health Grants Policy Statement says:

“Charges to NIH grant awards for the conduct of live vertebrate animal activities during periods of time that the terms and conditions of the grant award are not upheld are not allowable. Specific situations under which charges are not allowable are:

1. The conduct of animal activities in the absence of a valid Animal Welfare Assurance on file with OLAW.
2. The conduct of animal activities in the absence of a valid IACUC approval of the activity. Absence of IACUC approval includes failure to obtain IACUC approval, expiration, or suspension of IACUC approval.

. . . In cases where charges have been made for unauthorized animal activities, appropriate adjustments must be made to the grant to remove those charges.”

As you know, this project was suspended during July, 2017. I am working on the assumption that funding was suspended at that time, according to the policy listed above.

As you know, this project was initially funded in 2012. So, it was in either the 4th or the 5th year of the project. There is no reason to assume that these compliance issues started at some specific date in 2017. In fact, it may be reasonable to assume that this total failure in compliance relative to PHS policy was ongoing for 4 - 5 years.

Apparently a protocol was approved relevant to this project which included a specific room in which the protocol was to be performed, a precise kind of breeding procedures which did NOT include Trio breeding, a specific kind of euthanasia which was not cervical dislocation without anesthesia, aseptic technique, and full documentation of post-surgical anesthesia. However, this was not the project which was performed.

To refresh your memory, the Indiana University School of Medicine IACUC investigation found:

- "\* The PI was using a procedure room that was not in the approved protocol;
- \* The PI was using trio breeding and weaning at 28 days, which was not approved in the protocol;
- \* The PI was using cervical dislocation without anesthesia as a primary means of euthanasia, which was not approved in the protocol;
- \* The PI was not using aseptic techniques when conducting survival surgery; and
- \* The PI's surgical records were lacking documentation of post-surgical analgesia."

This project had an approved protocol, but it was virtually ignored, with the possible exception that the PI did remember to use the correct species of animals.

In short, this PI violated virtually every basic tenet of properly performed research, and in doing so also violated the approved protocol every step of the way, potentially for as much as five years. Everything from proper pain relief to aseptic technique to things as basic as proper record-keeping, and proper euthanasia were ignored. In short, this project was one large and ongoing unapproved procedure. As such, as long as these non-compliances were underway, since during that period all procedures were essentially unapproved procedures, all federal funding should be returned to the National Institutes of Health, potentially back to the very first day of the project. This could result in a refund to the National Institutes of Health that would exceed \$1.5 million.

Therefore, this project should be thoroughly investigated to ascertain how long these non-compliances have been underway, and any disallowance of funding should be backdated to the beginning of these non-compliances.

I have attached the relevant internal IACUC reports from the Indiana University School of Medicine, and I will look forward to the resolution of these matters by the National Institutes of Health.

I look forward to hearing from you in the near future about this matter.

Sincerely,



Michael A. Budkie, A.H.T.,  
Executive Director, SAEN

Attachments: 1 File containing an Indiana University School of Medicine report

A 4091-34



**INDIANA UNIVERSITY**

OFFICE OF THE VICE PRESIDENT  
FOR RESEARCH

July 24, 2017

Axel V. Wolff, M.S., D.V.M.  
Director, Division of Compliance Oversight  
OLAW/NIH  
RKL 1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982  
[olawdco@mail.nih.gov](mailto:olawdco@mail.nih.gov)

RE: Notice of Non-compliance for Assurance D16-00584 (A 4091-01): Indiana University School of Medicine

Dear Dr. Wolff:

This letter reports a new incident of non-compliance with PHS Policy and the Guide for the Care and Use of Laboratory Animals at the Indiana University School of Medicine for one of our IACUC protocols covering laboratory mice.

An issue of possible animal welfare was discussed at the June 27, 2017, and July 12, 2017, SOM IACUC full board member meetings. Please find a summary of the reported incident below.

At these SOM IACUC meetings, the committee discussed the findings of a Post-Approval Monitoring visit and an IACUC subcommittee lab inspection for one of our IACUC protocols. These inspection reports indicated that the IACUC inspectors found the following:

- The PI was using a procedure room that was not in the approved protocol;
- The PI was using trio breeding and weaning at 28 days, which was not approved in the protocol;
- The PI was using cervical dislocation without anesthesia as a primary means of euthanasia, which was not approved in the protocol;
- The PI was not using aseptic techniques when conducting survival surgery; and
- The PI's surgical records were lacking documentation of post-surgical analgesia.

After significant time in deliberation, the committee members determined that these issues qualify as protocol non-compliance. Further, the committee felt there was also an animal welfare concern because the animals did not receive the appropriate analgesia, resulting in the animals experiencing unnecessary pain and/or distress. With this, the IACUC voted to suspend the protocol.

The IACUC members were very concerned with the magnitude of the protocol non-compliance and decided that the PI and all protocol personnel approved on the protocol need do the following before the protocol suspension can be lifted:

1. Re-take all of IU's required on-line CITI training courses;

Axel V. Wolff, M.S., D.V.M.  
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PHS funds (4R01CA155086-05)  
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2. Take LARC hands-on trainings related to proper animal handling, rodent surgery and aseptic techniques, and rodent euthanasia;
3. LARC Veterinarians must observe the first five animal surgeries performed by anyone listed on this protocol after the above training has been completed;
4. PI must submit these five surgical records to the IACUC for review and approval;
5. PI must provide a detailed explanation regarding how these issues of non-compliance and animal welfare occurred; and
6. PI must submit a corrective action plan describing in detail how the PI will ensure that this will not occur in the future.

The SOM IACUC Chair followed up with the PI and staff to inform them of the decision made by the SOM IACUC.

This activity is supported by PHS funds (4R01CA155086-05), and the Program Officials and IU Grant Officers are copied on this letter.

Please do not hesitate to contact me if you have additional questions after receiving this letter.

Sincerely yours,



Fred H. Cate  
Vice President for Research  
Distinguished Professor and C. Ben Dutton Professor of Law

cc: **Secondary Individual** (Associate Vice President for Research Compliance)  
**Secondary Individual** (Chair, School of Medicine; Chairman, Department of Pediatrics)  
**Secondary Individual** (Grant Consultant, Office of Research Administration)  
Robert Considine, Ph.D. (School of Medicine, IACUC Chair)  
Debra Hickman, D.V.M., M.S., DAFLAM (Director, Laboratory Animal Resource Center)  
**Secondary Individual** (School of Medicine IACUC Director)  
**Secondary Individual** (Executive Director of RIICE)  
Chamelli Jhappan (NIH Program Official - [jhappanc@mail.nih.gov](mailto:jhappanc@mail.nih.gov))