DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive - MSC 7982
Bethesda, Maryland 20892-7982
Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
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September 6, 2017

Re: Animal Welfare Assurance
A3231-01 [OLAW Case 1U]

Dr. Christopher Agnew
Associate Vice President for Research
Director, University Research Administration and Compliance
Purdue University
610 Purdue Mall, Room 335
West Lafayette, IN 47907

Dear Dr. Agnew,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 22, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Purdue University. According to the information provided, OLAW understands that on two separate occasions, a total of eleven hamsters on a bacterial study died unexpectedly and the remainder in the study groups were euthanized. The antibiotic dose given as part of the study was lower than that described in the protocol and the monitoring intervals may not have been frequent enough to detect problems before the animals died.

The corrective actions consisted of initially amending the protocol to indicate that mortality is expected and amending it again to adjust the monitoring interval. Because of the antibiotic dose discrepancy and short period of morbidity, the Institutional Animal Care and Use Committee (IACUC) suspended the hamster portion of the protocol but allowed the mouse research to continue. If the hamster work is to continue, the investigator was advised to submit a separate protocol addressing the concerns.

Based on its assessment of this explanation, OLAW understands that measures have been taken to address the issue. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy. In future, please submit final reports to olawdco@od.nih.gov. Thank you for informing OLAW about this matter.

Sincerely,

Axel Wolff, M.S., D.V.M.

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

cc: IACUC Chair

A3231-14

PURDUE
UNIVERSITY

OFFICE OF THE EXECUTIVE VICE PRESIDENT FOR
RESEARCH AND PARTNERSHIPS

ASSOCIATE VICE PRESIDENT FOR RESEARCH,
REGULATORY AFFAIRS

August 22, 2017

Dr. Axel Wolff
Office of Laboratory Animal Welfare
National Institutes of Health
RKL1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892

Re: National Institute of Allergy and Infectious Diseases, grant number R01AI130186

Dear Dr. Wolff:

This is to provide OLAW with a report of an adverse event that resulted in the death of hamsters. The hamsters were experimental subjects in a research study that is supported by NIH funds with the grant number provided above. The principal investigator at Purdue in charge of this research is Prof. Mohamed Seleem, and the research is covered under an approved IACUC protocol, #1704001567, "Repurposing auranofin and ebselen for treatment of multidrug resistant pathogens."

Below is a detailed report provided by Prof. Seleem to Purdue's IACUC of the events that led up to the unexpected deaths of the hamsters;

- On July 28, 2017, 10 of 40 hamsters were injected with 10mg/kg clindamycin for *Clostridium difficile* infection.
- At 4 p.m. on July 29, the 10 hamsters were divided into 3 groups (4, 3, and 3) and given three doses of *Clostridium difficile* (1 $X10^5$, $4X10^5$ and $8x10^5$) colony forming units via oral gavage to adjust the dose that will be used for infection.
- Infected hamsters were checked regularly on July 29, July 30, and July 31 for signs of diarrhea or wet tail. There were no signs of diarrhea or wet tail, and the hamsters were doing fine during the last check at 11 p.m. on July 30.
- On July 31 at 9 a.m., a total of 8 hamsters were found dead in their cages (3, 2, 3). The other two infected hamsters were euthanized to avoid decline in health. Prof Seleem reviewed the established hamster model in the literature and found that mortality is expected and hamsters do not typically develop diarrhea when infected with *C. difficile*

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covers mice and this research may continue on the approved protocol.) Prof. Seleem will be asked to remove all references to hamsters on the above protocol before any work can proceed. Should he wish to continue this research in hamsters, he will be required to submit a separate, new protocol that addresses the issues and concerns that have become apparent during the past few weeks.

Sincerely,

Christopher R. Agnew, Ph.D.
Institutional Official
Associate Vice President for Research

cc: Janice Kritchevsky, Chair, IACUC
ondary Indivi IACUC Administrator
Bill Ferner, Attending Veterinarian

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