



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) 480-3387

May 12, 2023

Re: Animal Welfare Assurance
#A3693-01 [OLAW Case J]

Tariq Cheema, MD, FCPP, MMM
Medical Director and Vice President for Research
Allegheny-Singer Research Institute
320 East North Avenue
Pittsburgh, PA 15212

Dear Dr. Cheema,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 24, 2023, letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Allegheny-Singer Research Institute. According to the information provided, OLAW understands that a cohort of mice that had completed their experimental manipulations and showed no signs of cancer ("cured"), were re-inoculated without prior IACUC review and approval on an internally funded study.

The corrective actions consisted of the Principal Investigator (PI) expressing regret for the oversight and ensuring that IACUC approval will be secured for all procedures involving animals. The PI and research personnel will inspect animals daily to assess tumor growth and welfare and will maintain animal records in the room for the PI, research, and preclinical personnel to review, update and use. A revised amendment providing additional details, as requested by the IACUC, regarding the procedure for continuation of the study on the "cured" animals will also be resubmitted by the PI.

The establishment and application of policies and practices that are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals at the Allegheny-Singer Research Institute are commendable and avoid the perception of a double standard. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

Neera V. Gopee -S

Digitally signed by Neera V.

Gopee -S

Date: 2023.05.12 14:51:40 -04'00'

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Associate Director, Animal Welfare Policy
Office of Laboratory Animal Welfare
National Institutes of Health

cc: IACUC Chair



A3693-J

AHN Research Institute
320 East North Avenue
Pittsburgh, PA 15212-4722

April 24, 2023

Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare, National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982
Email: olawdco@mail.nih.gov

IACUC Protocol: (1081) Improving Vaccinia viruses for Cancer Immunotherapy
Funding Source: Internal (no Federal Funding)

To Whom It May Concern:

The AHN Research Institute (ASRI), in accordance with Assurance D16-00408/A3693-01 provides this report of noncompliance regarding an incident that mice who already completed experimental manipulations was re-inoculated, an activity not reviewed and approved by the IACUC in a Principal Investigator's (PI) above noted animal study protocol.

On March 16, 2023, the IACUC first received information that the continuation of experiments to inoculate animals who completed experimental procedures and showed no signs of cancer ("cured") were performed without prior IACUC review and approval. At the time of the discovery of the incident, the protocol did not describe procedures for continuing the experiment on these animals that appeared to be "cured" among other questions on use of animals. The IACUC discussed the incident and requested corrective actions from the PI as well as notifying the PI to immediately cease all non-approved animal activities until an amendment is approved for such activities.

During IACUC meeting on April 21, 2023, the Board reviewed the PI CAPA and had additional stipulations. It was noted that this protocol was internally funded and no federal funds were used in the conduct of the research protocol.

To address the situation, corrective actions were taken including the submission of an *Animal Study Protocol Amendment* to request a procedural change describing the continuation of experimental to inoculate animals who completed the procedures and showed no signs of cancer ("cured").

The PI expressed in a letter to the IACUC that this was an unfortunate incident and took responsibility for the noncompliance. The PI assured the IACUC that an incident of such nature would not occur again. The IACUC determined that this was an isolated incident and not a programmatic failure.

The following corrective action plan was implemented after the incident:

1. The PI submitted correspondence to the IACUC, dated April 4, 2023, expressing regret for the noncompliance incident of continuing the experiment again on "cured" animals that was not included in the protocol and it was an oversight.
2. The PI described corrective measures that had been implemented to prevent recurrence of an incident of this nature. The measures included
 - a. Insuring he and all research staff of the IACUC's requirement for securing approval for all procedures prior to work involving animals;
 - b. Daily inspection of animals to assess tumor growth and welfare and recording review in animal care records in the room;
 - c. Submission of amendment to protocol to add re-injection on "cured" animals
3. The PI assured the IACUC that he and all research staff will from now on carefully review and adhere to approved study protocols.
4. The PI submitted a request for a procedural change (*Animal Study Protocol Amendment*) to the protocol. The amendment describing the procedure to perform a continuation of experiment on the "cured" animals is in process as IACUC requires more details in the amendment.

At their meeting on April 20, 2023, the IACUC reviewed and added stipulations on the corrective action plan as submitted by the PI.

1. Animal records will be kept in room for PI/researchers and preclinical staff to review, update and use in assessing animal care and welfare;
2. PI and research staff will be retrained by Veterinarian staff including that Veterinarian has final authority over animal care
3. PI will resubmit revised amendment for IACUC to review and approval at their next meeting (May 2023).

The AHN Research Institute 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 contact IACUC Chair, Kevin Kelly, MD, PhD

(kevin.kelly@ahn.org) or

(b) (6)

(b) (6)

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Tariq Cheema, MD, FCPP, MMM
Medical Director and Vice President of Research
Institutional Official

cc: Principal Investigator (PI)
Department Chair

(b) (6)

AAALAC
File

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, May 9, 2023 12:30 PM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Noncompliance Report (AHNRI: Assurance D16-00408/A3693-01)

Good afternoon (b) (6)

Thank you for sending us this report, assigned OLAW case number A3693-J, and we will send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA ([pronunciation](#))
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: devora.mccoy@nih.gov

From: (b) (6)
Sent: Thursday, May 4, 2023 9:03 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] Noncompliance Report (AHNRI: Assurance D16-00408/A3693-01)

To Whom It May Concern,
Attached please find a noncompliance report from AHNRI IACUC (Assurance D16-00408/A3693-01).

If you have any questions or need anything else, please let me know.
Thank you,

(b) (6)