

Secondary Individual

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Eye Institute
Bethesda, Maryland 20892

Date: November 27, 2017
To: Dr. Rachel Caspi, Chair, NEI ACUC *RC*
From: Secondary Individual
Animal Program Director, NEI & NIMH
Subject: NHGRI Incident August 4, 2017

The following is a summary of my investigation into the incident that occurred Friday, August 4, 2017, in the Central Animal Facility (CAF).

Incident:

On Friday, August 4, 2017 the incorrect diet was provided to ~ 71 cages/205 mice in the CAF. As per the Technical Request received on October 17, 2016 these cages/mice were to receive a B12 deficient chow to be provided by the investigator, or their agent which will be dyed red by the manufacturer to distinguish it from the routinely fed diet. The diet was to be maintained in the refrigerator located in a shared small animal procedure room.

On Friday August 4, 2017, there was not sufficient diet in the refrigerator for all the study cages to receive the special diet. Rather than contact the investigator for additional feed, the caretaker believed he had identified additional "red" feed on another floor and fed the wrong diet to the animals in question. The caretaker assumed that this box of "red" diet that was found on another floor was the same diet that was used on the animal holding room floor, as back up B12 deficient diet had, at times, previously been stored in the fridge; and up until this week the B12 deficient diet was the only "red" diet within the facility. The caretaker proceeded to use the "red" diet located on other floor, not recognizing that it was a different diet, deficient in iron with normal levels of B12.

On Monday, August 7th, 2017 it was brought to the Small Animal Senior Team Leader's attention that the wrong special diet had been provided and the feed remaining in the cages was removed. As there was no vitamin B-12 deficient diet remaining, per the technical request the facility attempted to contact the agent via telephone at ~ 10 AM. After not being able to contact the agent, at ~1:30 PM the Facility Manager made the decision to add regular rodent chow to the cages. The agent was located at ~ 4 PM. The scientific staff decided to euthanize all the animals on the B12 deficient diet because of their 48-72 hours of exposure to diets with normal levels of B12 in them.

Observations:

1. Although both boxes of special diet were labeled with the type of diet, the diets look identical and the labels are small.
2. Current facility policies do not establish notification thresholds for when to inform investigators that the quantity of special diet on hand is running low.
3. Current facility policies do not establish the actions to be taken when the PI and/or facility runs out of the required diet. For example, was there another product which could be temporarily fed in the absence of sufficient B12 deficient rodent diet (i.e. peanuts, etc.) which would protect both the animal's well-being and study design.

Corrective Actions:

1. Refrigerators storing special diets will be labeled with signage indicating the nature of the diets stored within the unit.
2. In addition to the nature of the diet, manufacture, and expiration dates, each container of special diet will also be labeled with the investigators name and ASP number.
3. Ideally, a minimum of a one-two week supply of each special diet should be maintained at the floor level, accessible to the caretaker. An additional one-two week supply should be maintained at a secondary location, accessible to only the floor leaders and senior management.
4. When the stock is rotated and the secondary location empty, the PI shall be notified for additional product.
5. The quantity of product remaining in all storage locations shall be reported to Government management on each weekly report.
6. A "Special Diet Technical Request" form will be developed for the use of special diets which includes the contact information of both primary and secondary contact individuals, as well as another product(s) which could be temporarily fed in the absence of the special diet.
7. All staff will be retrained.

Summary:

The caretaker involved in this incident is no longer with our contract and all other staff have been retrained. It is our hope that these corrective actions will prevent a further occurrence of an incident of this nature.

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, January 04, 2018 2:14 PM
To: Clark, Terri (NIH/OD) [E]; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Denny, Stephen (NIH/OD) [E]
Subject: RE: Reportable Adverse Event - A4149-01 (NHGRI ACUC; 015-17) > revised: NEI ACUC

Thank you Terri. And thank you for your hard work on behalf of research, research animals and the Corps. We'll miss you.

We'll send an official response to this event soon and we'll be sure to send it to Steve.

Sincerely, Brent

Brent C. Morse, DVM, DACLAM
Acting Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: Clark, Terri (NIH/OD) [E]
Sent: Thursday, January 04, 2018 1:48 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Denny, Stephen (NIH/OD) [E] <stephen.denny@nih.gov>
Subject: FW: Reportable Adverse Event - A4149-01 (NHGRI ACUC; 015-17) > revised: NEI ACUC

Good afternoon – please find enclosed the close out memos for this event. I will be retiring effective tomorrow, January 5, 2018, so please forward the response and/or any questions to Dr. Steve Denny, Acting Director, OACU. Kind regards – Dr. Clark

Rear Admiral Terri R. Clark, DVM // Director, Office of Animal Care & Use, NIH
Assistant Surgeon General, USPHS Commissioned Corps // clarkte@od.nih.gov // Telephone # [REDACTED]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, November 02, 2017 2:26 PM
To: Clark, Terri (NIH/OD) [E] <clarkte@od.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Gottesman, Michael (NIH/OD) [E] <gottesmm@mail.nih.gov> [REDACTED] (NIH/OD) [E] <[REDACTED]@od.nih.gov>; Denny, Stephen (NIH/OD) [E] <stephen.denny@nih.gov>
Subject: RE: Reportable Adverse Event - A4149-01 (NHGRI ACUC; 015-17) > revised: NEI ACUC

No problem Terri. Thank you for updating us. We'll put this in the file. Brent

Brent C. Morse, DVM, DACLAM
Acting Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

National Institutes of Health

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From: Clark, Terri (NIH/OD) [E]
Sent: Thursday, November 02, 2017 2:04 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Gottesman, Michael (NIH/OD) [E] <gottesmm@mail.nih.gov>; Secondary Individual (NIH/OD) [E] <[REDACTED]@od.nih.gov>; Denny, Stephen (NIH/OD) [E] <stephen.denny@nih.gov>
Subject: RE: Reportable Adverse Event - A4149-01 (NHGRI ACUC; 015-17) > revised: NEI ACUC

Hi Brent – please note the response with come from the National Eye Institute's ACUC as they are responsible for the husbandry care these animals received. My apologies for not catching this for the initial report. Thanks Terri

Rear Admiral Terri R. Clark, DVM, DACLAM // Director, Office of Animal Care and Use, OIR // Assistant Surgeon General
USPHS Commissioned Corps // Telephone # [REDACTED] / Clarkte@od.nih.gov // <https://oacu.oir.nih.gov>

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, October 30, 2017 8:57 AM
To: Clark, Terri (NIH/OD) [E] <clarkte@od.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Gottesman, Michael (NIH/OD) [E] <gottesmm@mail.nih.gov>; Secondary Individual (NIH/OD) [E] <[REDACTED]@od.nih.gov>
Subject: RE: Reportable Adverse Event - A4149-01 (NHGRI ACUC; 015-17)

Hello Terri,

Thank you for this preliminary report. We will open a case file and await further information.

Sincerely, Brent

Brent C. Morse, DVM, DACLAM
Acting Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: Clark, Terri (NIH/OD) [E]
Sent: Friday, October 27, 2017 3:34 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Gottesman, Michael (NIH/OD) [E] <gottesmm@mail.nih.gov>; Secondary Individual (NIH/OD) [E] <[REDACTED]@od.nih.gov>
Subject: Reportable Adverse Event - A4149-01 (NHGRI ACUC; 015-17)

Hi Brent – I was informed recently that the National Human Genome Research Institute (NHGRI) ACUC had an adverse event that ultimately resulted in the euthanasia of numerous cages of mice.

Their ACUC will render a report in the near future.

Kind regards Terri

Rear Admiral Terri R. Clark, DVM, DACLAM // Director, Office of Animal Care and Use, OTR // Assistant Surgeon General
USPHS Commissioned Corps
Telephone # [REDACTED] terri@odhpn.gov / <http://oacu.odhpn.gov>