

Exhibit 10

- 10) January 4, 2013 letter from OLAW to UW discussing the responses and posing additional questions. More information was requested regarding the second set of allegations.

FOR US POSTAL SERVICE DELIVERY:

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6705 Rockledge Drive – MSC 7982
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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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January 4, 2013

Re: Animal Welfare Assurance
A3368-01 [OLAW Case 4P]

Name

Title

University of Wisconsin-Madison

Room # Bascom Hall – 500 Lincoln Drive
Madison, WI 53706

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 27, 2012 letter responding to my September 19, 2012 request for an assessment of allegations of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Wisconsin-Madison which were submitted by the People for the Ethical Treatment of Animals (PETA) and concerned a cat (L005/G07) on a deafness study. According to the information provided, OLAW understands that the School of Medicine and Public Health (SMPH) Animal Care and Use Committee (ACUC) determined the following:

- The study in question was not funded by NIH.
- All procedures conducted had been approved by the ACUC.
- The veterinary care and documentation were appropriate.
- Appropriate ACUC oversight was in place.
- The justification of animal numbers required additional information.
- The allegation involved activities which occurred in 2008 and numerous improvements have been made to the animal care and use program since then.

The following outlines specific responses to the questions posed in my original letter:

- 1) The veterinary care records maintained for animals are updated whenever an important clinical event occurs. No entries are made if there is no problem or veterinarian directed activity. Relevant animal records retained at SMPH include clinical records (Treatment and Progress), sick animal reports and cards, daily observation logs, and irregular (i.e. unexpected) animal observation sheets. The veterinary staff enters all clinical related information although investigators may record treatments in the clinical record. The clinical and sick animal reports contain all information regarding an animal's health. Separate research related records are kept by the investigators and include information on study related animal issues.
- 2) Lack of entries in the clinical record reflect the absence of any condition of clinical importance. Any condition requiring follow up will be performed by a veterinarian or under a veterinarian's direction.

- 3) All protocols address humane endpoints. The veterinary staff is authorized to treat, remove from study, or euthanize animals as needed. The current version of the protocol in question describes the euthanasia criteria in much greater detail. Treatment plans are developed in conjunction with the veterinarians if unanticipated adverse events occur. This cat was under ongoing treatment for the chronic infection which was localized and not systemic. The condition could not be resolved and the animal was ultimately euthanized.
- 4) The analgesic regimen on this study included routine post-operative administration as well as provision of pain management by veterinarians when clinically warranted. Cat L005 received antibiotic treatment and had the infected site cleaned. There were no signs of pain and analgesic treatment for the wound was not necessary.
- 5) A non-invasive, nonsurgical two hour auditory brainstem response procedure was performed under ketamine and acepromazine. A reference to “put in chamber” refers to placing the cat into an acoustic recording chamber, not placing a head cap. This activity was compliant with the description in the approved protocol.
- 6) During one procedure the cat was intubated and anesthetized. Apparently the endotracheal tube became detached from the anesthetic machine tubing during animal repositioning which caused the anesthetic depth to lighten. The tube was reconnected and the deep anesthetic plane was restored. There was no negative impact to the cat and it recovered appropriately. Reference to an anesthetic mask was a mistake in the entry in the anesthetic log. The research and veterinary staff was retrained on keeping accurate records.
- 7) All staff working with research animals is required to complete appropriate training before starting any animal activities. Training is tracked centrally and includes regulatory orientation, medical records, occupational health and safety, species-specific topics, and surgery if applicable. The Principal Investigator (PI) and staff on the cat study were appropriately qualified and trained. The veterinary staff assisted with anesthesia on this study and has subsequently increased its oversight. Refinements in anesthetic techniques are ongoing.
- 8) Investigators are required to justify the choice of species on the protocol form. Use of the cat model in this study was based on the physiological and anatomical similarity of the auditory system to humans. The reference in the original protocol relating to publication and funding was not intended to serve as a justification for the number of animals proposed for use. The PI was directed to amend the protocol addressing the justification of the numbers of animals to be used. The study examines the numbers of neurons needed for statistical significance and therefore the justification presented was accepted by the ACUC.
- 9) The protocol in question was revised and approved by the ACUC and is still active. The anesthetic regimen was refined in consultation with a veterinary anesthesiologist. All staff listed on the protocol has been appropriately trained, animal observation sheets are used for daily documentation, study endpoints have been revised, the number of cats used has been decreased, there is greater veterinary oversight of the procedures, and new treatment and critical care rooms have been established. Protocol review and oversight by the ACUC has been enhanced and ACUC members receive ongoing training. The investigator training program continues to be enhanced and animal care staff receives training on recognizing signs of pain and distress in all species.

Based on its assessment of these explanations, OLAW has a better understanding of the facts involved in this study. Regarding the statement that this study was not PHS-supported, please provide further explanation regarding the entry in the protocol form line #13 which states that the funding source is NIH. In the copy provided by PETA the grant number and title were redacted. Please provide an un-redacted version of this page and provide additional information regarding the funding source for this study for the version of the protocol covering cat L005 as well as its current funding status.

OLAW received a second allegation of noncompliance from PETA concerning additional cats on this study which was accompanied by copies of clinical health records from 2006 to 2008. Specifically, nine cats (G03, G04, G12, 21, 26, 28, 31, 32, 33) were identified with various health concerns. Please have the SMPH ACUC address the following additional questions:

- 1) Are or were any of these cats involved in a PHS-supported study?
- 2) Have any refinements been made to this study to decrease the post-surgical infection associated with the head cap implants?
- 3) Did any of these cats reach an established weight loss threshold? What are the current end point criteria for this study, including weight loss?
- 4) What specific clinical signs are listed in the protocol to help determine when analgesics are necessary?
- 5) Have any alternative methods (which decrease pain/distress) been evaluated or implemented in this study over the past five years?

Please provide a final or interim report by **February 8, 2013**.

Sincerely,

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

Axel Wolff, M.S., D.V.M.
Director
Division of Compliance Oversight

cc: [Redacted Name], [Redacted Title]
[Redacted Name], [Redacted Title]
[Redacted Name], [Redacted Title] USDA-APHIS-AC

Wolff, Axel (NIH/OD) [E]

From: [REDACTED] (NIH/NIDCD) [E]
Sent: Monday, November 26, 2012 10:48 AM
To: Wolff, Axel (NIH/OD) [E]
Subject: RE: November 5, 2012 Complaint from PETA re UW-Madison

Thanks, Axel. Please continue to keep us informed as appropriate.

Name

From: Wolff, Axel (NIH/OD) [E]
Sent: Friday, November 23, 2012 7:28 AM
To: [REDACTED] Name [REDACTED] (NIH/NIDCD) [E]
Subject: RE: November 5, 2012 Complaint from PETA re UW-Madison

Hi [REDACTED] Name

It is difficult for me to predict the outcome and timeline of investigations. Because I combined all of these cat cases into one, I don't foresee this ending very soon. Open cases are not available under FOIA and many go on for months.
Axel

From: [REDACTED] Name [REDACTED] (NIH/NIDCD) [E]
Sent: Tuesday, November 20, 2012 4:17 PM
To: Wolff, Axel (NIH/OD) [E]
Subject: RE: November 5, 2012 Complaint from PETA re UW-Madison

Thanks, Axel. Will you be able to give us advanced notice of when the NIH's determination on the case(s) will be provided? [REDACTED] Name at UW said in a media interview that he expected that we would have a determination in early November. I believe that that was before we received the second complaint. We'd like to be forewarned to the extent possible and appropriate.

Thank you,

Name

Name

Title

(office)
Telephone # (direct)
(mobile)

Name @nih.gov

From: Wolff, Axel (NIH/OD) [E]
Sent: Thursday, November 08, 2012 7:45 AM
To: [REDACTED] Name [REDACTED] (NIH/NIDCD) [E]
Subject: RE: November 5, 2012 Complaint from PETA re UW-Madison

Hi [REDACTED] Name

I have acknowledged receipt to PETA of this new set of allegations and have combined them with the previous cat case. OLAW will follow up on any new items as well as continuing to investigate the original complaint. You may be getting another barrage of public emails on these additional cat cases.

Axel

From: [Name] (NIH/NIDCD) [E]
Sent: Wednesday, November 07, 2012 1:51 PM
To: Wolff, Axel (NIH/OD) [E]; [Name] (NIH/OD) [E]; [Name] (NIH/OD) [E]; [Name] (NIH/OD) [E]; [Name] (NIH/OD) [E]; [Name] (NIH/OD) [E]; [Name] (NIH/OD) [E]
Cc: NIHInfo (NIH/OD)
Subject: FW: November 5, 2012 Complaint from PETA re UW-Madison
Importance: High

Hello,

I realize that Dr. Wolff has received this directly, but I wanted to be sure everyone was looped into this additional inquiry. As noted below and in the complaint, these allegations are new and distinct from those set forth in our September 12, 2012 complaint regarding the same experiments. (The letter names other animals, etc.)

Please advise if there is action needed from the NIDCD. Thank you,

[Name]

[Name]

[Title]

[Telephone #] (office)
[Telephone #] (direct)
[Telephone #] (mobile)

[Name]@nih.gov

From: Battey, James (NIH/NIDCD) [E]
Sent: Monday, November 05, 2012 5:01 PM
To: [Name] (NIH/NIDCD) [E]; [Name] (NIH/NIDCD) [E]
Subject: FW: November 5, 2012 Complaint from PETA re UW-Madison
Importance: High

FYI, these folks are real persistent,
Jbat

From: Jeremy Beckham [<mailto:JeremyB@peta.org>]
Sent: Monday, November 05, 2012 4:59 PM
To: Wolff, Axel (NIH/OD) [E]; Battey, James (NIH/NIDCD) [E]; Collins, Francis (NIH/OD) [E]; NIDCDInfo
Subject: November 5, 2012 Complaint from PETA re UW-Madison
Importance: High

November 5, 2012

Axel V. Wolff, M.S., D.V.M., Director
Division of Compliance Oversight
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James F. Battey, Jr., M.D., Ph.D., Director
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Francis S. Collins, M.D., Ph.D., Director
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9000 Rockville Pike
Bethesda, MD 20892

Via e-mail: wolffa@od.nih.gov; batteyj@nidcd.nih.gov; francis.collins@nih.hhs.gov

Dear Dr. Wolff, Dr. Battey, and Dr. Collins:

Attached please find a complaint from PETA regarding apparent violations of the Public Health Service's *Guide to the Care and Use of Laboratory Animals*, U.S. Government Principles, and the NIH Grants Policy Statement. These violations are related to the use of cats in sound localization experiments as part of an NIH-funded project at UW-Madison.

Please be aware that the allegations in this complaint are new and distinct from those set forth in our September 12, 2012 complaint regarding the same experiments.

Please contact me should you have any questions. Thank you for your attention to this urgent matter.

Sincerely,

Jeremy Beckham

Research Project Manager
Laboratory Investigations Department
People for the Ethical Treatment of Animals (PETA)

Telephone # JeremyB@peta.org