Request and Response Regarding Identification of Errors of Fact

35) September 16, 2013 response from UW IO identifying and correcting errors of fact



Dr. Axel Wolff, MS, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
RKL1, Suite 360
6705 Rockledge Drive, MSC 7982
Bethesda, MD 20892-7892

16 September 2013

Dear Dr. Wolff,

Thank you for the opportunity to review the draft report. We are pleased with OLAW's determination that the allegations in the PETA complaint were unsubstantiated. We further appreciate OLAW's assurance to the University and the public that appropriate veterinary care has been provided to animals involved in the studies, the investigator and staff were properly trained, IACUC oversight of the studies was appropriate, and that the animals referenced in PETA's complaint were in excellent health and did not show any signs of pain or distress.

Overall we feel that the draft report presents a fair and accurate picture of the research and the results of OLAW's review. Per your cover letter, we would like to call your attention to a few factual errors and suggest modifications to the text to remove statements that are inaccurate or prone to misinterpretation.

Before getting to the substance of the draft report, please note that the University of Wisconsin-Madison is referred to as "UW-M" throughout the draft report. That acronym is commonly used to refer to another institution in the University of Wisconsin System, the University of Wisconsin-Milwaukee. The University of Wisconsin-Madison is typically identified as either "UW-Madison" or simply the "UW." To avoid any confusion or misdirected attention

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toward our Milwaukee colleagues, please refer to the University of Wisconsin-Madison as "UW" or "UW-Madison".

With respect to the substance of the draft report, below please find the portions that we feel are inaccurate or misleading.

First Allegation

Section entitled "Findings and Evaluation"

Under the heading **Veterinary Care**, second bullet point, second sentence, please change "acoustic recording chamber" to "acoustic recording room". The term "chamber" has a second meaning in the context of this research, which led to PETA's confusion about the procedure the cat was undergoing in the first place.

Under the heading "Justification of Animal Numbers," second sentence, please change the final phrase "and to decrease the number of cats used" to "and to conform the description of number of animals used to actual usage." The original protocol requested up to 30 animals/year, but in reality, 13 animals total have been used in the studies since 2008.

Second Allegation

In the introductory paragraph, first sentence, please revise the end of the sentence reading "involving nine additional cats on this study" to "involving nine additional cats in this laboratory." The animals in the two allegations were involved in different studies. The first allegation involved one animal in a study not funded by NIH. The nine animals involved in the second allegation were in a related but different sound localization study funded by NIH.

In the introductory paragraph, third sentence, please revise the phrase "former UW-M veterinarian who was involved with this study" to "former UW-Madison veterinarian who claims to have been involved with this study." As written, this phrase is misleading because it implies strongly that it is a fact that the former veterinarian, had a meaningful role in the veterinary oversight of the animals referenced in the complaint. Although UW-Madison has never seen the specifics of Name 's complaint because the text of his complaint was redacted from records supplied by USDA, PETA's press release regarding Name 's complaint suggests that Name s "corroborating allegations" grossly overstated his role in the studies. Specifically, the press release quotes Name as saying: "I saw this research firsthand. Many of these cats suffered unnecessarily, and I made my concerns known to the principal investigator, colleagues and the UW-School of Medicine and Public Health [animal experimentation oversight committee] at the time. ... I'm confident a second, focused review of the surgical records by [the USDA] would show the same concerns the veterinary staff observed during my time at Wisconsin, and during my later review of these medical records." In fact Name was never assigned to work with the animals on this study. In a survey of the many thousand clinical record entries for the protocol in question, only approximately 15 notations were made by in an on-call or substitute capacity. It should also be noted Name that not a single one of Name 's few entries raised any concerns regarding the welfare of

the animals. There is absolutely no documentation of any kind that Name raised any concerns regarding "unnecessary suffering" or other concerns related to the welfare of the animals to either the principal investigator or the IACUC as a result of his contact with the animals. We cannot prevent Name from overstating his role in the studies, or falsely indicating he raised animal welfare concerns when the records show otherwise, but we feel it is misleading and false for the report to repeat as fact PETA's claim that he was "involved" with the studies.

Please note that the second USDA inspection did not occur on November 16, 2012 as stated. November 16, 2012 was the date of the second PETA complaint to USDA. USDA was on campus for two blocks of days in early- and mid-December. One December visit was in response to the PETA complaint and the second was a routine inspection that addressed additional material and other facilities. It is our understanding that findings from both December visits were combined in the single report you cite, which is dated January 16, 2013 at the end of the report.

Section entitled "USDA Report," 3rd bullet point.

Regarding animals with MRSA infection, please change wording from "one died" to "one was euthanized." "Euthanized" is the word used in the USDA report. In the context of the sentence, the word "died" strongly implies that the animal died without treatment, when in fact the animal was humanely euthanized after it was determined that it was not responding appropriately to treatment.

USDA Report - Bullet point 9

The bullet point is correct, but we wish to provide the following clarifications. As part of an unrelated routine inspection, UW-Madison was cited for the thermal burn incident based on a review of information contained in UW-Madison's clinical records. The thermal burn had already been reported to OLAW in July of 2012, five months before the USDA inspection. Thus, none of the PETA allegations resulted in a citation, and the only citation issued was for an event that UW-Madison had already reported to federal agencies. This was confirmed by a USDA spokesman in response to press inquiries.

We need to correct an error in our July 5, 2012 self-report, which stated that the thermal burn occurred during surgery. The procedure was completely non-invasive and painless. The anesthetic was used solely for chemical restraint because microphone recordings obtained from the animal's ear required that it not move its head.

Section entitled "Study Suspension of Invasive Animal Studies."

Please change this section heading to "Suspension of Invasive Animal Procedures." In fact, the study was not suspended, only invasive procedures. The PI has continued to conduct the behavioral work on the study and collect study data, which OLAW observed during the visit to UW-Madison.

Section entitled "OLAW Site visit and Recommendations, second bullet point of recommendations subsection.

Please change "standard operating procedures (SOP) should be developed" to "standard operating procedures (SOP) should be refined." The PI already had SOPs in place addressing the matters referenced in this bullet point at the time of the complaint. These were refined following consultation with veterinary staff from USDA, NIH and UW-Madison School of Veterinary Medicine. The refined SOPs were approved by the IACUC.

Section entitled "Summary," first sentence.

Please delete the word "generally." PETA's complaint made no specific allegation regarding infections, and UW-Madison received no citations for any of the specific allegations raised by PETA.

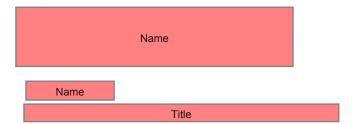
Regarding OLAW's recommendation for enhanced infection control, we recognize that infections are a factor with chronic explant preparations. As OLAW confirms in its findings regarding the second allegation, (last bullet point), infections are infrequent in this study. In fact, for the seven animals currently on study the average rate of infection is one every 3.8 years. We always welcome suggestions from OLAW and others to help us continually refine our practices regarding infection control and treatment.

Exhibits

- 12) The correct date of this report is January 16, 2013.
- 25) The text of the October USDA inspect report indicates that it was a "focused inspection" (i.e., in response to the PETA complaint). No citations were issued.

Thank you again for the opportunity to comment on the draft report. Please let me know if your have further questions.

Sincerely,



Wolff, Axel (NIH/OD) [E]

From:

Wolff, Axel (NIH/OD) [E]

Sent:

Tuesday, September 17, 2013 10:37 AM

To:

Name

Subject:

RE: UW-Madison response

Thank you for your careful review of this document, completion.

Name

I will send you a copy of the final report upon

Axel Wolff

-----Original Message-----From: Name [mailto:

[mailto: Name @wisc.edu]

Sent: Monday, September 16, 2013 6:00 PM

To: Wolff, Axel (NIH/OD) [E] Subject: UW-Madison response

Dr. Wolff,

Please find attached our comments regarding the OLAW report on sound localization studies at UW-Madison.

Thank you for the opportunity to comment.

Sincerely,

Name