25) September 2012 PETA rebuttal to UW statements.

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Friday, September 28, 2012 11:39 AM
To: 'Justin Goodman'
Subject: RE: Addendum to complaint re University of Wisconsin-Madison

Hello Mr. Goodman,

OLAW acknowledges receipt of this email and attached documents. I will add the first 16 pages to the initial complaint filed on behalf of PETA by Mr. Beckham which already includes the remainder of the attachments. As the initial complainant, Mr. Beckham will receive a final assessment from OLAW upon completion of this investigation.

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

From: Justin Goodman [mailto:JustinG@peta.org]
Sent: Friday, September 28, 2012 10:32 AM
To: Wolff, Axel (NIH/OD) [E]
Cc: Rockey, Sally (NIH/OD) [E]
Subject: Addendum to complaint re University of Wisconsin-Madison

Dear Dr. Wolff,

On September 12, 2012, People for the Ethical Treatment of Animals (PETA) submitted a formal complaint to your office regarding the abuse of cats in sound localization experiments at the University of Wisconsin-Madison (UW). Your office confirmed receipt of this complaint in an email to PETA on the same day.

On September 17, 2012, UW released a document on its website allegedly refuting some of PETA's allegations. Because OLAW typically requests that institutions conduct their own investigations of animal welfare concerns, UW may have shared this document or the information contained in it with you or a member of your staff.

We would like to bring to your attention that UW's claims are untrue and misrepresent facts found in their own internal records. Attached is a point-by-point response to UW's allegations referencing the relevant veterinary records and other documentation. The document corroborates our original allegations of likely violations of the PHS Policy and provides evidence of additional potential violations that were not previously brought to your attention.

Thank you for your time and consideration. Please contact me should you have any questions.

Sincerely,

Justin Goodman, M.A.
Associate Director
Laboratory Investigations Department
People for the Ethical Treatment of Animals
Telephone # | JustinG@peta.org

PETA Response to University of Wisconsin-Madison's Claims about Cruel Sound Localization Experiments on Cats

September 2012

1. **UW misleadingly states that, "In this case, the cat had two surgeries: one for cochlear implants, a surgery commonly performed in deaf humans to restore hearing…"**

Unlike humans who undergo cochlear implantation, **there was nothing wrong with Double Trouble's hearing prior to the surgery – experimenters intentionally deafened her during this procedure**. To do this, experimenters cut into Double Trouble's head behind both of her ears and exposed her bullae – which are bony chambers located behind a cat's ear that enclose the structures found in the inner ear. After exposing this structure, experimenters inserted a tube into Double Trouble's inner ear and injected neomycin sulfate into both of her inner ears to deafen her.[1] Neomycin is an antibiotic that is sometimes found in topical medications. When it's applied to the inner ear, neomycin destroys the cochlea and leaves an animal with profound deafness.

2. **UW misleadingly states that the second surgery was done, "to place a device on her head to keep recording instruments stable."**

UW's description of this procedure is vague. During this second surgery, experimenters took a stainless steel post that protruded from a base and attached it to Double Trouble's head by cutting into her skin and gluing and screwing the base onto her skull.[2] Double Trouble would live for months with this grotesque contraption protruding from her head and the wound around this post was the breeding ground for the bacterial infection that would persist for months and eventually prompt experimenters to euthanize her.

Additionally, it is deceptive for UW to construe the purpose of the headpost to keep "recording instruments" stable. In the protocol approved by UW, the experimenter referred to this device as a "head holding device,"[3] and that is exactly what the purpose of the device was. It was used to immobilize Double Trouble's head—not equipment—during experimental sessions where she would be awake and conscious, for several hours at a time.

Further, UW omits any mention of the surgery in which eye coils were implanted in Double Trouble's eyes. If Double Trouble did not have coils implanted in her eyes, this would be a

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[1] UW-Madison IACUC-Approved Protocol "Behavioral and Physiological Studies of Sound Localization." Question 17, pages 7-8. Attached as Exhibit A.
[2] Ibid. Question 28, page 12.
[3] Ibid.

deviation from the protocol, as the protocol repeatedly states that the eye coil implantation is to be conducted on **"all"** cats and occur during the same surgery as the headpost implantation. The protocol is also explicit that this procedure is to occur **prior** to the implantation of the cochlear devices so the cat can be behaviorally trained prior to deafening and the cochlear implant surgery:

> "Multiple surgeries are necessary for this experiment since we will need **one surgery to implant the eye coils needed for training, another to implant to cochlear implant after it is trained**, and a third to implant the recording chamber for neuronal recordings. There will be at least several months between the **initial** implantation of the eye coils and the cochlear implant surgery. Then, there will be at least several more months between the cochlear implant surgery and the implantation of the recording chamber."[4] [Emphasis added.]
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> ...
>
> "The initial procedure is done under sterile conditions with the cat deeply anesthetized with isoflurane/oxygen (above) to install a device for holding the head and coils of wire around the eyeball..."[5]
>
> ...
>
> "In order to train the animals, we must implant the eye coils and head holder so a surgical procedure is needed...**[O]ne surgery consists of implanting the eye and ear coils and the head restraint device, and a second surgery is needed to implant the recording chamber.** Second, in some animals we have had trouble with breakage of the eye coils which requires that they be removed and reimplanted. These cats will then undergo additional surgeries. Third, in some of the pinna de-efferentation experiments we will study the behavioral effects of de-efferentation, which requires the initial surgery to implant the eye coils and head restraint so that the animal can be trained. Only after training is complete, which may require up to several months of time, can the pinnae be immobilized in a second surgical procedure. Four, we will also compare the responses of cells in a normal cat with the same population of cells in the same cat with the pinnae immobilized. These cats will require a third surgery to de-efferent the pinnae following a few months of physiological recording. **Fifth, the cats with cochlear implants must undergo surgery in order to be trained behaviorally before they are deafened and given cochlear implants. In order to be trained behaviorally, they must first undergo the standard first surgery of head holder and eye/pinna coil implantation.** After deafening, they must then undergo the cochlear implant surgery. We endeavor to keep each of the surgical procedures as short as possible. **Not all cats will be subjects in all**

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[4] Ibid. Question 17, page 8.
[5] Ibid. Question 28, page 12.

experiments. All of them will undergo the first (head holder and eye and pinna coil implantation) and last procedures (recording chamber implantation)."[6] [Emphasis added.]

3. **UW misleadingly states, "After both surgeries, the animal was given pain medication and monitored closely to be sure the medication was working...."**

PETA never made any claims regarding the post-operative analgesics that were (or were not) given to Double Trouble. PETA's complaint stated that Double Trouble did suffer from a resilient bacterial infection that was a direct result of the head wound that experimenters inflicted upon her and the instrumentation that was implanted in her head. This is true. This open, bloody, infected wound surely caused immense suffering for Double Trouble, and her depressed behavior was likely a manifestation of this.

4. **UW inaccurately states that, "the mild neurological sign was twitching of the animal's ears. Clinical records from an hour-and-a-half later clearly state that it was resolved simply by turning down the volume on a hearing-aid-like-device."**

On August 13, 2008, Double Trouble's Treatment and Progress Record notes that she was experiencing tremors and twitching of the ears and head. Two days later it was noted that she was pacing. She wasn't observed again by UW's veterinary staff for over a month. On September 19, 2008, her record states: "asymmetry to the face - left eye/eyelid."[7] The photographs obtained by PETA also indicate that there is an asymmetry to Double Trouble's face and her left eye/eyelid appears askew.

UW did not respond to or even acknowledge PETA's claim that Double Trouble's facial asymmetry was likely the result of neurological damage. UW experimenters should have been aware that implanting two cochlear devices in Double Trouble's head carried a distinct risk of damaging Double Trouble's facial nerve. In 2004 – four years prior to Double Trouble's surgery – experimenters at Johns Hopkins University published a paper titled "An Animal Model for Cochlear Implants"[8] where they discussed implanting cats with cochlear devices similar to those used in Double Trouble:

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[6] Ibid. Question 30, page 14.
[7] UW-Madison. Treatment and Progress Record for Double Trouble, entry dated 19 Sep 2008. Attached as Exhibit B.
[8] Kretzmer EA, Meltzer NE, Haenggeli CA, Ryugo DK. An animal model for cochlear implants. Arch Otolaryngol Head Neck Surg. 2004;130(5):499-508. http://archotol.jamanetwork.com/article.aspx?articleid=647466.

> An important consideration in cochlear implant surgery is avoiding the facial nerve in the approach to the cochlea. The facial nerve exits the temporal bone through the stylomastoid foramen, which in the cat is a small fenestration in the bulla a few millimeters posterior to the external auditory canal. Injury to the facial nerve, quantified by impaired outer eyelid functioning, was observed in 1 animal.

Based on the protocol approved by UW, experimenters did not identify this potential adverse outcome. There is no mention of this possibility, no discussion of how the experimenter intends to avoid this outcome during Double Trouble's surgery, and indeed, in Double Trouble's Treatment and Progress Record, it states that the lab ascribed her facial asymmetry as related to "overstimulation" of her cochlear implants rather than damage to her facial nerve.

In our complaints to NIH and USDA, PETA called attention to Double Trouble's September 19, 2008 veterinary record entry because it is evidence that Double Trouble likely suffered nerve damage. UW has chosen to ignore this.

Additionally, it is inaccurate for UW to describe a cochlear implant as a "hearing-aid-like-device." The technology in a cochlear implant is completely different than a hearing aid. A hearing aid simply amplifies sound that goes into the listener's ear. A cochlear implant, on the other hand, transforms speech and other sounds into electrical energy and this signal is transmitted directly to an implanted receiver and then to electrodes in the inner ear. If the "volume" was too loud on Double Trouble's device, her auditory nerve was being over-stimulated, which can cause extreme discomfort, pain, and headaches.

5. **UW perplexingly states that, "Neither a recording chamber nor electrodes were inserted into the cat's head or brain at any time. The 'electrodes' referred to were surface electrodes placed on the skin of the neck and shoulder area for an Auditory Brainstem Response (ABR) procedure. The same auditory test is routinely performed on human newborns, and is harmless and painless."**

If this statement is correct, it represents two deviations from the approved protocol.

PETA believed this record was for the implantation of a recording chamber and microelectrode because the experimental protocol that UW approved states that **all** cats used in this experiment will undergo this procedure, because of the timing and duration of the procedure, and because the log for that procedure contains the phrases "put in chamber" and "electrodes inserted."[9]

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[9] UW-Madison. Procedure Log for Double Trouble, dated 21 Nov 2008. Attached as Exhibit C.

If Double Trouble never was implanted with a recording chamber or microelectrode, this is a deviation from the approved protocol. It also means that the experimenter was never able to obtain any physiological data for the experiment, which further supports PETA's claim that the experiment was useless.

Further, if UW was conducting the ABR procedure on Double Trouble in November 2008, this too was a deviation from approved procedures and likely a violation of federal law. The experimental protocol states that the ABR procedure will only take place "once before the surgery to gather baseline data on the hearing cat, and again 10 days into the deafening procedure to test for any residual hearing."[10] Yet, UW has now highlighted that this was performed more than five months after Double Trouble was deafened.[11]

6. UW states that, "Since the infection did not cause generalized illness in the cat, it would not interfere with the research."

It is clear from UW records that the complications from Double Trouble's infection were substantial and did interfere with the experiment; the stated reason UW staff provided for euthanizing her was that the she developed a bacterial infection, not because the experiment was complete.[12]

7. UW falsely states that, "PETA offers a misleadingly edited version of the clinical record...throughout the study, the animal ate and drank normally, produced normal urine and feces, and was bright, alert, and active."

In PETA's complaints to the USDA and the NIH, which UW has apparently seen and used as the basis for its public response, PETA included Double Trouble's full unedited clinical record in the exact form that it was provided to PETA by UW. PETA is more than happy to share this clinical record with anyone who wishes to see it and already has shared this full record with reporters. These records detail Double Trouble's ongoing health problems that were caused by the surgical and experimental procedures she was subjected to.

UW's claim that Double Trouble was fed normally stands in stark contradiction to the school's own records. **The experimental protocol states that the cats used in this experiment will be deprived of food for up to 5-6 days** in order to 'motivate' them during behavioral training and lab testing:

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[10] UW-Madison IACUC-Approved Protocol "Behavioral and Physiological Studies of Sound Localization." Question 17, page 8. Attached as Exhibit A.

[11] UW-Madison. Procedure Log for Double Trouble, dated 21 Nov 2008. Attached as Exhibit C.

[12] UW-Madison. Treatment and Progress Record for Double Trouble, entry dated 5 Dec 2008. Attached as Exhibit B.

"We control access of food to the animals in their home cages for the period that they are being trained and tested and feed them only during the behavioral training and testing in the lab. This is necessary to motivate them to do the behavior. If they are not food deprived they will not perform the behavioral task…Training sessions last 1-4 hours for 5 or 6 days/week and the cats are allowed 100 gms/day of food over the weekend."[13]

Regarding her overall health, UW staff regularly noted that Double Trouble was not eating normally, her feces appeared soft, her bowel movements infrequent, she was twitching, experiencing tremors, pacing, suffering from an infected bloody head wound for weeks, and she appeared depressed. Below are some of the entries that demonstrate Double Trouble's immense and protracted suffering for nearly six months:

DATE	**DESCRIPTION**
6/20/08	No feces in pan. Animal slightly atatxic [exhibiting symptoms of a dysfunction of the nervous system, such as poor coordination] and dehydrated.
6/21/08	Lethargic. Still eating canned food and attempting to eat dry food but seems to be having some trouble. No feces noted.
6/22/08	Slightly less lethargic than yesterday, has not eaten much. Feels thin.
8/13/08	Reported for mild tremors, not as social. Animal is resting. Mild twitching of ears and head. Slightly more movement when noise made. Slight head tilt to the right. Mild neuorologic sign, possibly related to cochlear implants.
8/15/08	Reported for pacing. Animal is pacing in cage…Possibly agitated, unknown cause.
9/19/08	Lab staff reported asymmetry to the face – left eye/eyelid…Lab staff thought may have related [sic] to electrical stim[ulation].
10/6/08	Wire loose from right side of jacket – playing with cord overnight/this a.m.? Small plastic piece found on cage floor; wire placed back into jacket and lab was contacted.
10/23/08	Cranial wound shaved, small hole – draining…w/ moderate tissue swelling around.

[13] UW-Madison IACUC-Approved Protocol "Behavioral and Physiological Studies of Sound Localization." Question 17(c), page 9. Attached as Exhibit A.

10/24/08	Cranial head wound open, moist w/bloody purulent discharge, moderate swelling….Per DVM, flushed wound cranial head with chlorhexidine solution, small amount of discharge expelled.
10/25/08	Minor swelling and discharge at head wound
10/26/08	Wound red and slightly moist.
10/27/08	Swelling around cranial wound increased. Purulent and bloody discharge expelled from cranial wound, swelling around wound opening increased. Soft feces in litter pan. Animal appears slightly depressed today. Per lab – reactive infection have been anecdotally reported w/these cranial electrodes.
10/28/08	Abdominally palpated – bowels slightly thickening. Soft stool. Flushed wound. Abscess secondary to chronic instrumentation appears to be healing.
10/29/08	Flushed with dilute betadine for cranial wound. Expelled purulent and bloody discharge from wound. Stool soft.
10/30/08	Small amount of soft stool in pan; flushed head wound with dilute betadine, moderate amount of viscous purulent discharge.
10/31/08	Flushed head wound w/dilute betadine, small amount of thick purulent discharge, moderate thickening of tissue around wound. Sedated…careful dissection of fistulated area on head revealed electrode connector with small piece loose…Skin over connector (original incision site) thickened. Placement of surgical subcutaneous drain difficult w/out full anesthesia & careful dissection around electrodes. *[Note: it appears that here UW staff inserted a surgical drain in Double Trouble's head. A surgical train is a tube inserted under the skin to remove pus, blood, and other fluids from a wound].*
11/01/08	Very small amount of purulent discharge from wound on head.
11/02/08	Wound on head scabbed, no discharge, but slightly swollen.
11/03/08	Approx 2cm lump on top of head associated with open wound and surgical incision, when pressure applied, moderate amount of thick yellow/red purulent discharge.
11/04/08	Wound on top of head scabbed over, soaked with dilute betadine then

	flushed with the same, small amount of purulent discharge.
11/05/08	Cranial wound cleaned with betadenie and flushed with dilute betadine, small amount of purulent discharge.
11/06/08	Flushed wound top of head w/diluted betadine solution, < .5 cc discharge expressed
11/07/08	Flushed cranial opening with dilute betadine and expelled purulent discharge.
11/09/08	Wound on head is clean, dry & scabbed. Removed scan & flushed ascess w/a smalla mount of dilute betadine solution. Small amount of purulent discharge expelled. Wound on head slightly moist but clean with no active discharge.
11/10/08	Soaked head wound/fistula with dilute betadine, scab removed, flushed with dilute betadine, small amount of purulent discharge evacuated.
11/11/08	Small scab removed from cranial wound, small amount of yellowish cloud discharge expelled. Flushed wound.
11/12/08	Cranial wound flushed…small amount of yellow purulent discharge.
11/13/08	Removed scan off cranial head wound – small amount yellowish purulent discharge evacuated.
11/14/08	Wound continues to heal [which could form an abscess]. Communicated with PI & lab staff regarding plan for cat. If continues or worsens, need to carefully place surgical drain under anesthesia.
11/16/08	Small amount of purulent discharge expelled from cranial wound.
11/18/08	Soft feces in litter pan. Cranial wound soaked & large scan removed – small amount of purulent discharge evacuated.
11/19/08	Lab staff called. Exudate from [illegible] site on left top of head [Note: this is the beginning of a second head wound in Double Trouble]. Purulent discharge left. Had been in lab all day. Communicated w/PI regarding planned testing.
11/20/08	Right cranial wound – scab removed & flushed with dilute betadine, moderate amount of thick purulent discharge evacuated. Left cranial wound soaked w/dilute betadine, small amount purulent bloody

	discharge. No feces in pan, normal urine.
11/21/08	Both right and left cranial wounds flushed with betadine dilute solution; right wound large amount of thick yellow purulent discharge evacuated, left wound moderate amount of thick bloody purulent discharge evacuated. No feces in box.
11/22/08	No discharge or scabbing observed. Slight swelling and redness on both right and left cranial wounds. Soaked wounds and flushed with dilute betadine solution.
11/23/08	Scan ob right side cranial wound. Soaked and removed scab. Flushed both right and left cranial wounds with dilute betadine.
11/24/08	Right cranial wound scabbed and dry. Left cranial wound closed with swelling, notable to expel discharge.
11/25/08	Flushed both left and right cranial wounds with dilute betadine. Bloody purulent discharge from left cranial wound.
11/26/08	Right cranial wound mostly closed with tiny amount of purulent, red discharge. Left cranial wound open, flushed with dilute betadine. Skin surrounding left cranial wound appears irritated, redness apparent. Expelled purulent discharge.
11/27/08	Left cranial wound – enlarged bump – 1 ½ cm, when palpated, large amount of purulent and bloody discharge evacuated. Right cranial wound – small amount of purulent discharge.
11/28/08	Cranial wounds on top of head moderate amount of red/yellow crusting. Both open wounds left and right flushed with sterile saline. Small amount of yellow purulent discharge evacuated from right side, moderate amount yellow purulent bloody discharge from left side. Small purple bruise on media side of left wound. Left pinna tissue wound swelling and redness decreased.
11/29/08	Right and left cranial wounds and yellow/red crusting cleaned topically. Both wounds flushed with sterile saline.
11/30/08	Cleaned top of head. Large amount of drainage from left side – yellow/red crusting. Flushed both wounds w/sterile saline.
12/1/08	Cleaned and flushed wounds with sterile saline. Applied triple antibiotic ointment to both wounds. Mild discharge from left cranial wound,

	decreased redness around wound.
12/2/08	Cleaned cranial wounds, expelled purulent discharge from left cranial wound. Attempted to flush cranial wound with sterile saline, animal was not cooperating, small amount of flush did go into wound. Cleaned head and applied TAO (triple antibiotic ointment) to both wounds.
12/3/08	Cleaned cranial wounds topically…Attempted flushed of wounds with sterile saline – animal not cooperating…Increased crusting & discharge from left side of headcap.
12/4/08	Cleaned cranial wounds topically…flushed with sterile saline. Moderate amount of purulent discharge from left side. Right side – no discharge.
12/5/08	Cleaned cranial head of scabs. Expelled purulent discharge from left cranial wound and flushed with small amount of sterile saline. Redness increased around left cranial wound. More sensitive to touch. Met with [REDACTED] regarding prognosis. Right sign not working, infection not responding to treatment. Recommended terminal.

8. **UW misleadingly states, "Contrary to PETA's claim, the numbers of animals requested and approved in the protocol was 30 over a 3-year period, not 30 per year."**

PETA has stated that "up to 30 cats per year" have been used in this experiment because the UW experimenter stated that she/he has historically used 30 cats per year and in the protocol he/she offered a justification for using this many cats:

> "We have been studying the auditory system for over 30 years here at UW-Madison and **the number of animals requested represents an average taken over a number of years**…[i]t is not only more practical but also more realistic to justify the number of animals based upon past experience. **While we have averaged about 30 cats/year**, this number is quite variable, depending upon the experiments that are being done at any given moment. This number allows us to collect enough data to keep up a productive publication record that ensures our constant funding from NIH over these 30 years."[14] [emphasis added]

[14] UW-Madison IACUC-Approved Protocol "Behavioral and Physiological Studies of Sound Localization." Question 12, page 3. Attached as Exhibit A.

As we pointed out in our complaints to the USDA and NIH, in answer to a previous question in the same protocol, the experimenter stated that she/he uses 15 cats per year on average.[15] It is also true that in another place in the protocol, the experimenter requested 30 cats over a three year period.[16] In other words, the experimenter offered justifications for three completely different numbers of animals in the protocol and the UW IACUC approved the protocol despite this obvious inconsistency. This is further evidence that the experimental protocol was poorly written, ill-conceived, and should have never been approved. These discrepancies are likely violations of the federal Animal Welfare Act.

9. UW falsely states that, "the researcher provided a detailed scientific justification of animal numbers based on the number of brain cells needed to do he research [sic], and correlated this to the number of animals required."

The experimenter's justification for the use of 30 cats in this experiment is both inadequate and unscientific. In fact, the experimenter states that he/she *can't* reliably estimate the number of animals she/he will use based on scientific criteria because "it is not possible to state how many neurons are required to reach statistical viability since that depends upon the questions that we are addressing and the differences we see between different neurons."[17]

According to the USDA, "stating that the number of animals to be used cannot be determined using statistical criteria or tests, because of the nature of your field or research, is not an appropriate explanation of how the numbers requested was determined."[18]

Without a scientific basis justifying the number of animals used in the experiment, the IACUC approved the number of cats requested based "on past experience," "the demands of critical reviewers for our manuscripts," and to ensure that the experimenter can "keep up a productive publication record" – all of which were offered as alternative justifications for the number of cats requested but none of which constitute a statistical or scientific justification for the basis of the experiment.

10. UW falsely states, "The USDA and other regulators provide no specific guidance about how to justify animal numbers."

The USDA's Animal Welfare Information Center (AWIC) is a clearinghouse of information regarding animal care and proper compliance with federal law serving laboratories and other

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[15] Ibid. Question 11(c), page 3.
[16] Ibid. Question 9(a), page 2.
[17] Ibid. Question 12, page 3.
[18] United States Department of Agriculture Plant Health Inspection Service Inspection Report for University of California-San Francisco dated 24 Jan 2012. Attached as Exhibit D.

AWA-licensed institutions. AWIC offers guidance and references to peer-reviewed literature discussing how to properly design an animal experiment and statistically justify the number of animals in an experimental protocol.[19] Federal law requires that experimenters using animals be trained in how to use these resources and specifically recommends AWIC.[20] UW's claim that no guidance exists to explain how to justify animal numbers just indicates that it is not familiar with the regulations it is required to adhere to – even though UW has previously been cited by USDA for failing to provide adequate justifications for animal numbers for at least 3 experimental protocols since 2007.[21] UW even paid a fine to the USDA in 2005 for violating this and other provisions of the AWA.

It is astonishing that UW still claims it has no understanding on how to comply with this provision of the AWA and this fact strongly suggests that UW still has not corrected its repeated deficiencies in this area. In light of this, PETA encourages USDA to increase the severity of its enforcement action against UW if PETA's allegations are substantiated.

Also, as PETA pointed out in its government complaints, the USDA has previously stated:

> **"Stating that the number of animals to be used cannot be determined using statistical criteria or tests, because of the nature of your field or research, is not an appropriate explanation of how the numbers requested were determined unless an acceptable alternative explanation is provided. Citing requirements for publication of manuscripts is also not an adequate explanation for the need to use a specific number of animals for experimentation."**[22]

Multiple universities have policy documents published on their own websites instructing experimenters how to properly justify the numbers of animals to be used in a study.[23]

11. UW misleadingly states, "In the approved protocol, the researcher describes in detail why non-animal alternatives and other animal models cannot be used to address the scientific question in play. The justification is logical and appropriate in the context of the specialized nature of this work."

The experimenter made a naked assertion that non-animal alternatives would not suffice for the experiment, but she/he did not describe *why* in any detail. Further, there are no

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[19] http://www.nal.usda.gov/awic/pubs/IACUC/stat.htm
[20] 9 C.F.R. § 2.32 (c)(5).
[21] United States Department of Agriculture Plant Health Inspection Service Inspection Reports for University of Wisconsin-Madison dated 12 Apr 2007 and 20 Jun 2007. Attached as Exhibit E.
[22] United States Department of Agriculture Plant Health Inspection Service Inspection Report for University of California-San Francisco dated 24 Jan 2012. Attached as Exhibit D.
[23] For example, see http://www.research.uh.edu/Home/Division-of-Research/Research-Services/ACO/Policies-and-Guidelines/Justification-of-numbers-references.

indications that the experimenter considered the most common non-animal methods that are already in use at other institutions for investigating the neural mechanisms of sound localization, nor are there any indications that she/he considered widely-available refinements to the experiment to avoid conducting specific invasive and potentially painful procedures on cats.

As we outline in our complaint, the non-animal research methods for this type of research that are being employed at other institutions include imaging techniques such as positron emission tomography (PET) and near-infrared spectroscopy (NIRS). Furthermore, contrary to the experimenter's statement that "[r]ecordings from human subjects are not feasible since the information...requires invasive recordings,"[24] invasive neural recordings using human volunteers are possible, using intracranial electroencephalography (iEEG). PETA gave numerous examples of this in its complaints to USDA and NIH.

Despite the fact that these imaging technologies are well-known, have existed for years, and are already being employed in the pursuit of sound localization research at premier research institutions around the world, there is no indication that the experimenter even considered these alternatives to the use of animals in this experiment.

Further, as PETA outlines in its government complaints, the AWA requires that the investigator consider alternatives not only to animal use generally, but also alternatives for each "potentially painful and distressful procedure."[25] For example, instead of steel eye coil implants, many experimenters use a non-invasive infrared method for tracking eye movement in cats and other animals that obviates the need to perform any surgery and "excels with even higher precision than the other methods."[26,27,28] This refinement allows experiments to avoid causing animals any pain and distress related to the initial implant surgery, coil replacement surgery (which is common because the hardware is fragile) and potential chronic eye irritation, pain, and injury. There is no evidence in the approved protocol that these non-invasive methods were even considered or any explanation why they could not be used.

12. UW misleadingly states, "Suggestions for alternatives offered by PETA could not answer the specific questions being asked by the investigator, and therefore are not considered valid alternatives."

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[24] UW-Madison IACUC-Approved Protocol "Behavioral and Physiological Studies of Sound Localization." Question 16(a), page 4. Attached as Exhibit A.

[25] http://www.aphis.usda.gov/animal_welfare/policy.php?policy=11.

[26] Körding KP, Kayser C, Betsch BY, König P. Non-contact eye-tracking on cats. J Neurosci Methods. 2001 Sep 30;110(1-2):103-11.

[27] Girard P and Koenig-Robert R.. Ultra-rapid categorization of fourier-spectrum equalized natural images:macaques and humans perform similarly. PLoS One 6:e16453 (2011).

[28] Ben-Simon A, Ben-Shahar O, Segev R. Measuring and tracking eye movements of a behaving archer fish by real-time stereo vision. J Neurosci Methods. 2009 Nov 15;184(2):235-43.

The Animal Welfare Act *requires* that available alternative methods be sought and considered *in the experimental protocol* and an explanation be offered as to *why* these alternatives are not valid. The experimenter failed to do this in the protocol and UW fails to do this in its rebuttal to our complaint. UW's self-serving and empty assertion that animals must be used amounts to a simple "trust us." Indeed, the alternatives suggested by PETA are already in use at other institutions doing similar experiments.

13. **UW misleadingly states, "Every animal is observed everyday by animal care staff and/or veterinary staff. Animal care staff maintains daily logs of those animal checks, and contact veterinarians if they notice anything abnormal. PETA examined medical records, not daily logs. Physicians don't visit their patients when they are not sick, nor do veterinarians clinically examine an animal every day unless there is a health reason to do so."**

As PETA pointed out in its complaints to the USDA and NIH, there are several lengthy gaps in Double Trouble's Treatment and Progress Record during the period she was being observed for serious health problems. These gaps in recordkeeping indicate that veterinarians still were not regularly examining her even though there was, "a health reason to do so." Also, if additional written records exist for routine observations of Double Trouble, UW did not provide them to PETA in response to our public records request.

14. **UW states, "PETA claims that during a surgery fluid began filling the animal's lungs, the animal stopped breathing, and that if the proper tube had been used the fluid would not have accumulated. They also claim the cat woke up during surgery, because its anesthetic gas was disconnected so the fluid could be removed. In the surgery, the records show that the animal was intubated before the surgery started. There was fluid accumulation inside the tube, which affected the cat's breathing, and require brief removal of anesthetic so that the tube could be cleared...."**

UW is splitting hairs. Whether the fluid accumulation occurred in Timmy's (a.k.a. 'Cat 33') lungs or in his trachea, it indicates a failed endotracheal intubation. Whether this error was a result of utilizing the wrong size of tube or because UW staff did not properly place the tube, this error is the result of incompetence of UW staff. The unfortunate result of this incompetence is that he was not adequately anesthetized during the duration of the surgery.

UW states that:

> ***...There was no fluid in the lungs. The depth of anesthesia may have become lighter while the anesthetic gas was disconnected, but the record indicates that the cat remained asleep for the duration of the surgery.***

As the record states, fluid began to fill Timmy's trachea, and he could not breathe properly, so his anesthesia had to be removed, as the surgical log states: "Cleared trachea of fluid, isoflurane removed to clear trachea."[29]

Also, contrary to UW's statement here, Timmy's procedure log is clear when it says "Cat woke up" for the entry at 4:35, which was during the middle of a surgery where eye coils were being implanted in his eyes and a head post screwed to his skull. Timmy woke up before experimenters could suture his wounds. Additionally, his heart rate jumped from 119 to 180 during this entry, another sign that his anesthesia wore off.[30]

15. UW misleadingly states, "PETA claims that an anesthetic mask was improperly used. The PETA investigator who reviewed the records must not have noticed the entries stating that a tube was placed in the trachea at the beginning of the procedure, and not removed until the animal was recovering from the procedure. Even if a mask was momentarily used to assist with the anesthetic gas being delivered through the tube, the mask was never a primary method for delivering anesthesia, and the animal was fully anesthetized during the entire procedure."

In its response, UW fails to account for why the anesthetic mask was removed or whether or not the mask's removal was intentional. Nor does UW explicitly state whether or not the removal of the anesthetic mask did or did not, in fact, cause Double Trouble to wake up, even if it was only used to "assist" with the anesthetic gas being delivered via the endotracheal tube.

The surgical record, on the other hand, is clear when it says **"Anesthetic mask came off, animal showed signs of waking."**[31] This entry appears immediately after an entry remarking that experimenters had cut into Double Trouble's head and exposed her skull, and immediately before an entry where experimenters drilled into her skull.

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[29] UW-Madison. Procedure Log for Timmy, a.k.a. Cat 33, dated 17 Dec 2008. Attached as Exhibit F.
[30] Ibid.
[31] UW-Madison. Procedure Log for Double Trouble, dated 11 Jun 2008. Attached as Exhibit G.

16. UW falsely states, "Just as in human surgery, the heart rate of the patient is carefully monitored and if the patient is "getting light" or "waking up" the heart rate will go up. In this case when the "mask" comment was written in the record, the heart rate remained low."

The opposite of this is true. Double Trouble's surgery was approximately 6 hours long and during this time experimenters documented her heart rate 22 separate times. Of those 22 written notations, the highest heart rate recorded–190–was for the entry when they observed her anesthetic mask came off. Indeed, 190 is higher than Double Trouble's recorded heart rate prior to the induction of anesthesia. Also, Double Trouble's respiratory rate for that entry–21–was also higher than any other point during the procedure and higher than that recorded prior to the induction of anesthesia.[32] Double Trouble's sharp increase in heart and respiratory rate when her anesthetic mask came off is further evidence that she did, in fact, wake up during this invasive procedure, and indicates that the anesthetic mask was important for ensuring she was being administered adequate anesthesia, as already implied by her surgical log.

[32] Ibid.

Investigation of charges against UW-Madison by PETA.

On 12 September 2012, People for the Ethical Treatment of Animals (PETA), an animal rights organization, filed complaints with the U.S. Department of Agriculture and the National Institutes of Health Office of Laboratory Animal Welfare (OLAW) about studies conducted at University of Wisconsin-Madison involving a cat. The complaints were reviewed by multiple individuals, including research animal veterinarians, and all of PETA's claims were found to be unsubstantiated, as documented below.

1) *PETA alleges that the University of Wisconsin-Madison did not ensure procedures minimized discomfort, distress and pain. To support the allegation, PETA states that the animal "was subjected to several invasive surgeries on the eyes, ears and brain. As a result of these multiple surgeries, the animal's health rapidly deteriorated."*

    a) In this case, the cat had two surgeries: one for cochlear implants, a surgery commonly performed in deaf humans to restore hearing; and a second to place a device on her head to keep recording instruments stable. After both surgeries, the animal was given pain medication and monitored closely to be sure the medication was working.
    b) Throughout the study, the animal ate and drank normally, produced normal urine and feces, and was bright, alert and active. This indicates she was generally in good health. When any device extends through the skin, such as head posts in humans designed to stabilize the neck after trauma, the surrounding skin remains susceptible to infection. This must be diagnosed and treated in both animal and human patients. In this case, appropriate veterinary care was provided at all times, and the cat's health was closely attended to, as documented in the clinical record.

2) *PETA alleges that there was a "neurological sign," and implies that this issues was unaddressed.*

    In this case, the mild neurological sign was twitching of the animal's ears. Clinical records from an hour-and-a-half later clearly state that it was resolved simply by turning down the volume on a hearing-aid-like-device.

3) *PETA alleges, "More than three months after her surgery, the records describe the cat's wound as "open, moist w/ bloody purulent discharge [with] moderate swelling." Even after this observation [of the head wound never healing] the cat was still used in an invasive procedure where a recording chamber was implanted into the head and electrodes were inserted into the brain."*

    As noted in the medical records, the discharge from the incision was diagnosed and treated within two hours. Neither a recording chamber nor electrodes were inserted into the cat's head or brain at any time. The 'electrodes' referred to were surface electrodes placed on the skin of the neck and shoulder area for an Auditory Brainstem Response (ABR) procedure. The same auditory test is routinely performed on human

newborns, and is harmless and painless. Since the infection did not cause generalized illness in the cat, it would not interfere with the research.

4) *PETA alleges that a bacterial infection developed in the surgical wound starting on or about Oct. 22, 2008, but that despite this, researchers continued to use the animal for several weeks. The records indicate that the infection was never brought under control and one of the last entries in [the cat's] records states that the cat "appear[ed]...depressed."*

PETA offers a misleadingly edited version of the clinical record. The complete entry states that the "animal appears slightly depressed today" during a morning observation. PETA failed to point out that the record states the cat was bright, alert, and responsive by that same afternoon, and bright, alert, and responsive the previous day. Furthermore, for both humane reasons and to follow the principles of the "3 R's" (reduction, refinement, and replacement) due diligence was exercised to eliminate the need to replace the animal with another. There was a continuous and extensive effort to diagnose, treat and manage the condition that took place throughout the fall of 2008.

5) *PETA alleges that the cat was not euthanized when experiencing severe or chronic pain or distress.*

The written record supports the fact that appropriate veterinary care and treatment was utilized to minimize discomfort, distress, and pain, and that when deemed appropriate, the animal was humanely euthanized. Veterinary-recognized clinical signs and symptoms of pain and distress were not observed in the cat. The clinical records show the cat continued to eat, drink and behave normally. A localized chronic infection did occur and was treated. When treatment efforts were deemed ineffective, the decision was made to humanely euthanize the animal in early December of 2008.

6) *PETA alleges that the investigator did not justify the number of animals needed for the experiments.*

a) Contrary to PETA's claim, the numbers of animals requested and approved in the protocol was 30 over a 3-year period, not 30 per year.
b) PETA complains that there is no scientific or statistical basis for the numbers of animals approved, but rather the numbers were justified by the researcher as being the number of animals needed to successfully publish research papers. In fact, the researcher provided a detailed scientific justification of animal number based on the numbers of brain cells needed to do he research, and correlated this to the number of animals required. The oversight committee, the Institutional Animal Care and Use Committee (IACUC), accepted this description. It should be noted that, before any scientific paper is published, other scientists in the same field critically scrutinize it; this process holds researchers to very high standards and is a worthy yardstick with which to measure scientific research.
c) PETA claims that since the IACUC approved the requested number of animals, then the committee must not be following the law. The USDA and other regulators

provide no specific guidance about how to justify animal numbers. The committee routinely applies the "3Rs" (reduction, refinement, and replacement) to guide their deliberations on animal numbers. In the case of this work, the investigator applied the 3Rs, and significantly reduced the numbers of animals requested compared to earlier studies.

7) *PETA alleges the investigator did not consider alternatives to the use of animals.*

In the approved protocol, the researcher describes in detail why non-animal alternatives and other animal models cannot be used to address the scientific question in play. The justification is logical and appropriate in the context of the specialized nature of this work aimed at helping deaf people hear. Suggestions for alternatives offered by PETA could not answer the specific questions being asked by the investigator, and therefore are not considered valid alternatives. One research objective is to obtain sufficient data to build a computer model that would mitigate the use of animal models for this type of research.

8) *UW-Madison did not ensure that a significant change to the protocol was reviewed by the Institutional Animal Care and Use Committee (IACUC).*

PETA claims a surgery was performed using unapproved anesthesia medications. The procedure they refer to is the ABR, which is not a surgery. The anesthesia medications used for this ABR were appropriate and as described in the protocol.

9) *PETA alleges that the cat was not observed on a daily basis.*

Every animal is observed every day by animal care staff and/or veterinary staff. Animal care staff maintains daily logs of those animal checks, and contact veterinarians if they notice anything abnormal. PETA examined medical records, not daily logs. Physicians don't visit their patients when they are not sick, nor do veterinarians clinically examine an animal every day unless there is a health reason to do so.

10) *PETA alleges veterinarians did not provide guidance to the investigator regarding the care and use of animals, as evidenced by four examples of anesthesia wearing off in cats undergoing highly invasive surgeries, or not being administered at all.*

a) Two of the four examples cited were actually not highly invasive surgeries, but rather the same Auditory Brainstem Response tests described earlier. ABR tests are commonly performed on newborn human infants. A light level of anesthesia is preferred, and was administered as described in the approved protocol, so the assertion by PETA that these instances reflect inadequate care is incorrect.
b) In a third case, PETA claims that during a surgery fluid began filling the animal's lungs, the animal stopped breathing, and that if the proper tube (endotracheal tube) had been used the fluid would not have accumulated. They also claim the cat woke up during surgery, because its anesthetic gas was disconnected so the fluid could be removed. In this surgery, the records show that the animal was intubated before the

surgery started. There was fluid accumulation inside the tube, which affected the cat's breathing, and required brief removal of anesthetic so that the tube could be cleared. There was no fluid in the lungs. The depth of anesthesia may have become lighter while the anesthetic gas was disconnected, but the record indicates that the cat remained asleep for the duration of the surgery.

c) In a fourth case, PETA claims that an anesthetic mask was improperly used. The PETA investigator who reviewed the records must not have noticed the entries stating that a tube was placed in the trachea at the beginning of that procedure, and not removed until the animal was recovering from the procedure. Even if a mask was momentarily used to assist with the anesthetic gas being delivered through the tube, the mask was never a primary method for delivering anesthesia, and the animal was fully anesthetized during the entire procedure. Just as in human surgery, the heart rate of the patient is carefully monitored and if the patient is "getting light" or "waking up" the heart rate will go up. In this case, when the "mask" comment was written in the record, the heart rate remained low.