National Eye Institute Research Cruelty and Redundancy

By

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The use of primates in experiments funded by the National Eye Institute of the National Institute of Health is one of the most horrific and wasteful areas of experimentation funded by the federal government. Every year this area of highly invasive experimentation causes the suffering and death of hundreds of animals. Every five years the 53 grants in this highly redundant area of investigation waste approximately $100 million in federal tax dollars. Our investigations have revealed that these projects are underway in 26 laboratories spread throughout 15 states. They involve 46 researchers and have wasted 510 research years.

Similar methodologies are used by an additional 49 projects funded through both the National Institutes of Mental Health and the National Institute of Neurological Disorders and Stroke, likely utilizing a roughly equivalent amount of funding.

The technology used in these projects dates back to the 1960s. Indeed, many of these projects have been funded for decades. Two are over 30 years old, six are over 20 years old, and 13 are over a decade in age. This is old technology and should be abandoned.

The barbaric procedures use steel or titanium screws to bolt restraining bars and recording cylinders to the skulls of macaque monkeys. Eye coils are implanted under the skin. Conscious primates are forced to participate in the behavioral paradigms through the utilization of food and/or water deprivation while confined in restraint chairs.

Even though federal regulation of these laboratories is extremely lax, these projects have in many instances been tied to violations of the Animal Welfare Act. It is also common for facilities which utilize these procedures to have relatively high rates of meningitis and encephalitis, requiring that the primates spend extremely long periods of time on regimens of very strong antibiotics.

Just as the federal government allowed Wall Street to go essentially unregulated in many ways leading to the financial collapse which we now deal with as a nation, research laboratories are largely unregulated. Federal laws are so poorly enforced, or simply ignored, that practices which would land any non-scientist in jail for cruelty are commonplace in the laboratory setting.

The findings of this investigation will be presented to federal legislators as we seek a General Accounting Office investigation of the funding of primate experimentation within the National Eye Institute.

The information which formed the basis of this investigation has been posted on our website, and is made available today as part of what is the largest release of internal research documentation ever accomplished by an animal protection organization. All resource materials are available at: http://www.all-creatures.org/saen/grants-gov.html, including full-text versions of dozens of grant applications which were obtained through the Freedom of Information Act.
Materials list:

Grant Table

USDA Violations relevant to Neurological Research

Seattle Times Article Regarding USDA Violations @ University of Washington, Seattle

UCSF

Smith-Kettlewell Eye Research Institute

Princeton

Duke

Wake Forest

Vanderbilt

Ethical and Scientific Criticisms of Neurological Research Practices by Veterinarians and Primatologists

UCSF Primate Photo

MIT Primate Photo
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<td>R01 EY006558-17</td>
<td>CHRIS R. KANEKO</td>
<td>17</td>
<td>$2,768,625</td>
<td>UW SEATTLE Macaque</td>
<td>X</td>
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52 grants 45 Researchers $98,912,211 25 Laboratories

15 states 507 Research Years Spent
The University of Washington may have to pay back some federal research grant money because of ongoing oversight problems at its controversial primate-research center, UW and federal officials have confirmed.

The problems stem from unapproved surgical procedures done on monkeys during research funded by the National Eye Institute, a federal agency, said Nona Phillips, director of the UW's Office of Animal Welfare.

Documents obtained under public-disclosure laws cite dozens of such surgeries in the labs of neurosciences researchers studying the relationship between the brain and eye movement.

The UW says the problems amount to a paperwork glitch that inadvertently omitted mention of particular surgeries during revisions of research protocols, which must be approved by a UW committee before research can proceed.

The UW says it has taken steps to improve oversight, and the federal agency responsible for ensuring the "humane care and use" of animals in research, the Office of Laboratory Animal Welfare (OLAW), has said it is satisfied by those steps and has closed the case.

But the possibility that grant money may have to be refunded "is still under consideration and investigation," said Dr. Michael Oberdorfer, a program director at the National Eye Institute, part of the federal National Institutes of Health.

And activists who have long targeted the UW's primate center as cruel and inhumane say it proves the UW is not taking seriously orders to clean up its practices at the Washington National Primate Research Center on the UW campus.

"The fact that the UW characterizes this incident — 41 surgeries on 14 monkeys — as a clerical error seems unduly dismissive to me," said Debra Durham, the Seattle-based primate specialist for People for the Ethical Treatment of Animals (PETA).

"Ethically speaking, we can't afford to lose sight of the animals. For them, the difference between two surgeries and six or 10 is much more than paperwork."

Previous problems

The recent troubles are the latest in a long string of problems for the UW's animal-research facilities. In 1995, the university risked losing U.S. Department of Agriculture accreditation for its primate-breeding facility near Spokane when five baboons died of cold-weather exposure or thirst. The school paid a fine and closed the aging facility.

In late 2006, the UW was put on probation by the facilities accrediting agency, the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC). Although inspectors praised the UW for its veterinary care and medical record-keeping, they noted "serious deficiencies" in animal-research facilities in Seattle, including monkey labs that leaked steam from a cage-washing device, inadequate lighting, and lack of alarms to alert people in case of heating or air-conditioning failure.

The UW's Phillips said the university has corrected all the deficiencies, except those that require remodeling of the facility, and that's being planned. But the UW is still on probation from AAALAC.

The most recent problems were brought to the attention of federal agencies in late 2006 by a Cincinnati animal activist, Michael Budkie, who heads a group called Stop Animal Exploitation Now!, or SAEN. Budkie complained that certain monkeys used in neurosciences studies were being mistreated.

After a three-day visit in late October 2006, a USDA inspector dismissed most of Budkie's allegations but noted that "many discrepancies were uncovered" in animal research done by Albert Fuchs, a neurosciences researcher studying how the brain controls eye movement.

The inspector said some monkeys had received many more surgeries than were allowed in the protocols approved by the UW's animal-welfare oversight committee, the Institutional Animal Care and Use Committee, as well as surgeries that were "outside the realm" of the protocols.

Primate A01136, a rhesus macaque, for example, died after eight surgeries, including one that removed a section of its cranial bone and installed a recording cylinder on its brain with acrylic and screws. The approved protocol called for only two minor surgeries, with possible need for readjustment or repair.
Two other primates also had undergone more surgeries than called for in the protocols, the inspector said. In addition, the approved protocols didn't specify the way that researchers were supposed to drill through the monkey's eye-socket bone to run wires from an implant to a screw in the skull.

The inspector also criticized Fuchs for saying his animals had experienced no unexpected adverse events or deaths in the past year, even though the macaque called A01136 had died, apparently of hypothermia after surgery.

The federal OLAW office closed the UW's case in March 2007 but reopened it in May after PETA complained about more unauthorized surgeries and unacceptable sterilization of the implants being used.

The federal animal-welfare office told the UW to review five years' worth of neuroscience primate protocols and animal records. Phillips said that hadn't been done before because it was assumed the USDA inspector had identified all nonapproved procedures in her report.

That review found two additional researchers' labs had performed unauthorized surgeries — a total of 39 unapproved surgeries on 16 monkeys over four years.

**Figures uncertain**

Altogether, the grants for the three neurosciences researchers for the periods covered by the unapproved surgeries total several million dollars, though no one can agree on the exact figure.

The researchers say they're trying to learn how the brain controls movement, in an effort to improve treatment of stroke and other brain disorders.

Phillips said there is no indication the UW could lose entire grants. But she said it might have to refund what was spent on the unauthorized surgeries and care afterward, which the UW has calculated at more than $189,000.

Phillips said the unauthorized surgeries occurred because an update of research protocols mistakenly removed wording noting that if hardware placed in animals' heads broke or needed to be readjusted, later surgeries would be required.

As for the sterilization of implants, the UW said it has changed to a different sterilizing solution, even though it denies a problem with the old formula.

Phillips stresses that federal inspectors found no "animal mistreatment or animal suffering," and she expressed frustration that critics claim otherwise.

"The university has a clean slate on that," Phillips said.

In a letter to the UW on March 3, an OLAW director wrote that the agency was satisfied the UW "has implemented measures to correct and prevent recurrence of the original problem," and would inform PETA that the allegations it raised have been "appropriately addressed."
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(ix) Activities that involve surgery include appropriate provision for pre-operative and post-operative care of the animals in accordance with established veterinary medical and nursing practices. All survival surgery will be performed using aseptic procedures, wearing surgical gowns, masks, sterile instruments, and aseptic techniques.

A 2-cm x 2-cm site in the dorsal midline of the inguinal region was then injected with 1 ml of sterile saline. The incision was made with a 15-blade scalpel. The muscles were retracted, and the care of the animal was immediately initiated.

In all cases of emergency, a surgical team consisting of one surgeon, one anesthetist, and one scrub nurse will be on standby. The surgeon will be responsible for the surgical procedure, the anesthetist will be responsible for the anesthesia, and the scrub nurse will be responsible for the collection and disposal of surgical waste.

Surgical suits in use for procedures on live animals are not intended for use in the surgical suite. However, the surgical suits are not designed for use in the surgical suite. All surgical suits are designed for use in the surgical suite. All surgical suits are designed for use in the surgical suite. All surgical suits are designed for use in the surgical suite.
Water restriction study using monkeys revealed that one monkey received less than the protocol's minimum daily ration. The protocol states that primates should receive a minimum ration of 10 ozs of fluid per day. There were several instances in which the primate received between 6-9 ozs of water a day. The records indicated water was removed on a Sunday, times of water removal wasn't documented but the investigator stated at approximately 10 AM. The following day the animal received 6, 7, or 8 ozs of water. The investigator stated that attempts were made to provide the animal with enough water to reach the minimum daily ration of 10 ozs on each day as stated in the protocol but the animal refused the water and it was removed. It was later stated that the protocol may have been in error and the minimum amount of water should be 10 ml/day. This protocol should be reviewed and appropriate changes made for the well-being of the animals and that description of the proposed use of the animals followed.


3.56 (c) SANITATION.

(c) Housekeeping. Premises (buildings and grounds) shall be kept clean and in good repair in order to protect the animals from injury and to facilitate the prescribed husbandry practices set forth in this subpart. Premises shall remain free of accumulations of trash.

Machinery equipment was placed along side of clean empty animal enclosures in the cage wash room. The equipment was leaking oil into and through the surface of the cardboard box where it was located. The animal enclosures in direct contact with the box were being contaminated by the oil leaking out of the device. Contamination of animal enclosures with oil from discarded machinery may lead to illness in animals housed in those enclosures.

Sheet rock type of walls surfaces in the main hallway were flaking and chipping from contact with equipment. Much of the chipped or flaking surfaces were on the floor in the hallway.

Corrected during inspection by removal of equipment and cleaning and sanitizing the area where the equipment was located.

3.75 (a) (c) (e) HOUSING FACILITIES, GENERAL.

(a) Structure: construction. Housing facilities for nonhuman primates must be designed and constructed so that they are suitable and for the species of nonhuman primates housed in them. They must be kept in good repair, and they must protect the animals from injury, contain the animals securely, and restrict other animals from entering.

One group of primates housed in the Koret building were in cages with the squeeze shoots that did not lock and the animals were able to manipulate the squeeze shoots creating a smaller area. In the process of closing the shoot it would have been possible for a primate to injure a finger or arm between the gates as the shot was being closed. A piece of equipment was being secured to prevent the animal from being able to manipulate the enclosure and thus preventing possible injury.

Corrected during inspection.

(3) Cleaning. Hard surfaces with which nonhuman primates come in contact must be spot-cleaned daily and sanitized in

Prepared By:  
MICHAEL SMITH, V.M.O., USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER, Inspector ID: 5019

Received By:  

Title:

Date: AUG-07-2006

Date: AUG-07-2006
acconformance with 73.84 of this subpart to prevent accumulation of excreta or disease hazards.

A primate chair used to restrain primates during certain procedures was in a private room with brownish stains smeared on the side plexiglass wall and lower surface. The cleaning and sanitizing protocol described to me by the responsible person was that chairs are used daily and only cleaned on the weekends. There was no spot cleaning and/or sanitizing of the chairs during the week. The official SOP for the cleaning and sanitizing of the private chairs was provided to me during the inspection and either cleaning and sanitizing after each use or daily cleaning and sanitizing is required. The responsible person was not following the SOP for cleaning and sanitizing of equipment.

Corrected during inspection.

c) Storage. Supplies of food and bedding must be stored in a manner that protects the supplies from spoilage, contamination, and vermin infestation.

A storage container with primate feed supplements contained a discarded paper towel and a small piece of string. The primate feed supplements were in the original paper bag, use of feed storage containers to discard any trash does potentially compromise primate food supplies. Animal feed storage containers must be used for only feed storage which ensures freedom from contamination. Placement of feed containers near or around hand washing stations encourages the disposal of trash into the container. Placement of containers in areas away from sinks may help to eliminate dual usage.

Corrected during inspection.

Prepared By: MICHAEL SMITH, V.M.O., USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER, Inspector ID: 5019
Date: AUG-07-2008

Received By: 
Title: 
Date: AUG-07-2008
**INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).**

(c) IACUC Functions. With respect to activities involving animals, the IACUC, as an agent of the research facility:  
(1) Review, at least once every six months, the research facility's program for humane care and use of animals, using title 9, chapter 1, subchapter A-Animal Welfare, as a basis for evaluation;  
(2) Inspect, at least once every six months, all of the research facility's animal facilities, including animal study areas, using title 9, chapter 1, subchapter A-Animal Welfare, as a basis for evaluation.

IACUC facilit/program reviews of the research facility's program for humane care and use of animals did not identify an animal with screws implanted in the zygomatic arches, as a procedure not having a protocol. This animal was not identified by the IACUC or the attending veterinarians during inspections as one having unauthorized surgical procedures. There were no IACUC records, documents, amendments or protocols addressing a surgical procedure for implanting screws in those locations. Program reviews for humane care and use of animals and facility inspections must include visualization of animals and identification of abnormal devices or instruments or any deviations from the approved protocol. Systems should be in place to identify these types of violations of the Animal Welfare Act and Regulations.

Corrected by March 10, 2007.

(c) IACUC Functions. With respect to activities involving animals, the IACUC, as an agent of the research facility (7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities.

An investigator performed experimental surgical procedures on a primate without IACUC approval or veterinary consultation. The experimental surgical procedure was not successful, leaving a primate with one screw in each zygomatic arch and one in the back of the skull. A second surgical procedure was performed without IACUC approval to perform a second surgery. Significant changes in protocols resulting in deviations must be approved by the IACUC.

Corrected by March 10, 2007.

(d) IACUC review of activities involving animals. (1) In order to approve proposed activities or proposed significant changes in ongoing activities: the IACUC shall conduct a review of those components of the activities related to the care and use of animals.

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<tr>
<td>MICHAEL SMITH, V.M.D., USDA,APHIS,Animal Care</td>
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Page 1 of 2
animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing. Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements: (i) The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources, e.g., the Animal Welfare Information Center, used to determine that alternatives were not available;

The unauthorized experimental surgical procedure performed on a primate did not include a search for alternatives to procedures that may cause more than momentary or slight pain or distress to the animal. The primate in question had 3 screws, one in each zygomatic arch and one at the back of the skull, resulting from the unauthorized surgical procedure. There was no literature search done for alternatives to the procedure and there was no IACUC approval.

Correct by March 10, 2007

(d) IACUC review of activities involving animals (1) is to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing. Provided, however, that field studies as defined in part 1 of this subchapter are exempt from this requirement. Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements: (iv) Procedures that may cause more than momentary or slight pain or distress to the animals will: (B) involve, in their planning, consultation with the attending veterinarian or his or her designee;

Veterinary consultation was not requested nor received by the investigator to perform experimental surgery on a primate. The investigator was attempting to alter the surgical procedure to reduce the amount of dental acrylic on the skull of the primate. The surgical implantation of three screws, two on the zygomatic arch and another at the back of the skull were implanted in a primate. This new procedure was done without IACUC approval or veterinary consultation. The investigator determined that the procedure was not successful and performed the standard type of surgical procedure on the primate at a later date. The primate had two screws on each side of the face, that served no purpose. The Animal Welfare Act requires consultation with the attending veterinarian and also IACUC approval prior to performing procedures on animals used in research.

Correct by March 10, 2007

(a) A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following: (3) A complete description of the proposed use of the animals;

Protocol 04P01Y6S did not have an adequate description of the procedures performed on primates. The location of the implants in the skull and screws were not described in the protocol. The vague description allowed an investigator to place screws in various locations of the skull in attempts to refine the procedures. In doing so a primate was subjected to unapproved or unnecessary surgical procedures leaving screws in the face and head not used for any purpose. Protocols must be written so the description of the procedures and proposed use of animals is clear. If deviations are required the investigator must seek IACUC approval.

Correct by March 10, 2007.

Prepared By:

MICHAEL SMITH, V.M.O., USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER, Inspector ID: 5019

Received By:

Title:  

Page 2 of 3
2.31 \((c \times 2)\)

**INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).**

(2) Inspect, at least once every six months, all of the research facility's animal facilities. Including animal study areas, using title 9, chapter I, subchapter A-Animal Welfare, as a basis for evaluation.

***The semiannual facility inspections for the year 05 were done on April and November 05. The interval between both inspections exceeded the "at least once every 6 month" interval as required by the regulation. Corrected by: Next facility inspections***

2.33 \((b \times 2)\)

**ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.**

(2) The use of appropriate methods to prevent, control, diagnoses, and treat diseases and injuries.

***Animal # 27195 has skin rash on the lateral sides of the chest, the animal was itching at the time of inspection. The animal records didn't indicate any diagnosis or treatment although the problem was identified previously. Corrected by: 4/18***

3.83

**WATERING.**

Potable water must be provided in sufficient quantity to every nonhuman primate housed at the facility. If potable water is not continually available to the nonhuman primates, it must be offered to them as often as necessary to ensure their health and well-being, but no less than daily for at least 1 hour each time, unless otherwise required by the attending veterinarian, or as required by the research proposal approved by the Committee at research facilities.

***Animal # 991/1103 was offered water for 45 minutes on 4/16 and for 45 minutes on 4/17. Water scheduling is not justified at this time. Need to reemphasize the protocol to indicate that the animals on this protocol will be on water scheduling prior to the head implantation. Corrected by: 4/20***

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**Prepared By:**

NASRY FALTAS, D V M, USDA, APHIS, Animal Care

**Date:**

APR-17-2006

**Title:**

VETERINARY MEDICAL OFFICER

**Received By:**

INSPECTOR ID: 1062

**Date:**

APR-17-2006
3.83 WATERING.

Potable water must be provided in sufficient quantity to every nonhuman primate housed at the facility. If potable water is not continually available to the nonhuman primates, it must be offered to them as often as necessary to ensure their health and well-being, but no less than twice daily for at least 1 hour each time, unless otherwise required by the attending veterinarian, or as required by the research proposal approved by the Committee at research facilities.

***Nine primates on protocol were not receiving daily amounts of fluid consistent with the approved protocol. The approved protocol requires that each primate receive its baseline amount of fluid daily. While most of the primates were receiving nearly the baseline amount daily, they were not being supplemented to the full baseline amount daily in order to keep their task performance at an acceptable level. All primates received full fluid amounts at least two days/week. Two primates received much less than the baseline amount on workdays (approximately 50-60ml for "Otto" and 100-200ml for "Solly"). On some days, "Otto" received only 10-20ml of fluid. On Sundays, the approximate fluid amount for primates was about 70-100ml. Baseline amounts for primates varied, with the minimum being around 500ml/day. Body weights were taken at least weekly and remained stable. Hematocrits, blood chemistries, and physical exams were normal for all primates on semi-annual exams including the most recent which was done July, 2007. All primates did receive additional vegetables (low-water content ones such as yams, zucchini, corn, and spinach) every afternoon. All primates exhibited normal appearance and behavior on visual inspection. Need to ensure that all procedures being conducted have been fully reviewed and approved by IACUC. Correct by September 7, 2007.
2.31 (d) (1) (ii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources, e.g., the Animal Welfare Information Center, used to determine that alternatives were not available;

---Protocol involved the use of eye coils, but did not include an adequate alternative search for current alternative methods available. Key words searched did not include anything related to eye coils or eye movement recording. Need to expand alternative search to incorporate all appropriate keywords and also to explain why available alternatives were not used. Note: The investigator involved in this protocol is currently using an alternative to the eye coil on another more recently reviewed protocol. Correct by January 15, 2006.

Prepared By: F. BINKLEY, D. V. M., USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER

Received By: ____________________________

Title: ____________________________

Date: NOV-13-2005

2.31 (d) 1 (i)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31(d) IACUC review of activities involving animals.

(1) In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing; Provided, however, That field studies as defined in part 1 of this subchapter are exempt from this requirement. Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements:
(Also refer to Policy 11, Painful Procedures)

(i) Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals.

*The laboratory record for primate R.5715F (Protocol[BLANK]) dated May 21, 2006 shows that laboratory personnel performed a durascope. The laboratory record dated May 23, 2006 shows that another durascope was performed. The medical record for primate R.5715F states on May 25, 2006 that a veterinarian was called on May 24, 2006 regarding the primate "holding head after cleaning". A veterinary technician examined the primate and reported no concerns. Neither the laboratory record, the medical record or the controlled drug log show that any anesthetics or analgesics were administered before, during or after the cleaning/durascope procedure.

*The IACUC must assure that procedures within a protocol are designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research including provision for the use of analgesic, anesthetic and tranquillizing drugs where indicated and appropriate to minimize discomfort and pain to animals.

*The IACUC must assure that all procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals. Correct from this day forward.

This is a focused inspection reviewing non-human primate (NHP) surgeries.

Records reviewed: NHP protocols, NHP controlled drug logs, NHP surgical records, NHP medical records, NHP laboratory records, IACUC meeting minutes dated 11/11/06 and 11/27/06.

Inspection conducted by Susanne Brunskorst, VMO, Associate Director Division of Animal Care, clinical veterinarians, facility manager, principal investigators, IACUC chairman.

Exit interview conducted by Susanne Brunskorst VMO, Director Division of Animal Care and Associate Director Division of Animal Care.

Prepared By:  
Susanne Brunskorst, VMO, USDA, APHIS, Animal Care

Received By:  
VETERINARY MEDICAL OFFICER, Inspector ID: 1076

Date: DEC-18-2006

Date: DEC-18-2006
Medical Research Modernization Committee

P.O. Box 201791
Cleveland, Ohio 44120
216-283-6702

June 26, 2008

Michael E. Budkie, A.H.T.
PMB 280
1081-B State Route 28
Milford, Ohio 45150

Dear Mr. Budkie,

It is my understanding that veterinarians have previously noted that procedures such as prolonged water deprivation, restraint chairs, and induced infectious diseases cause substantial pain and/or distress. This raises obvious ethical issues, and there are legitimate concerns about whether researchers are accurately reporting these procedures to the USDA as category E procedures.

I would like to comment on the scientific issues raised by procedures that cause substantial pain and/or distress. It has been well-documented that stress profoundly influences the body’s reaction to manipulations, and this occurs in ways that are difficult to predict or quantify. Consequently, adding to the inherent difficulties associated with applying animal data to humans, pain and distress further undermines animal experimentation’s validity and value. If researchers deny the stress associated with research environments or protocols that induce pain and/or distress, they misrepresent their research in ways that can mislead those aiming to apply animal research results to humans. For example, humans who have not experienced the same pain and/or distress might react very differently to medical conditions that animal models purport to emulate.


Sincerely,

Stephen R. Kaufman, M.D.
MRMC cochair
TO WHOM IT MAY CONCERN

I am a primatologist with my academic training in biological anthropology. In 1973, I began an ongoing field study of the ecological adaptations of sympatric species of macaque monkeys (Macaca spp.) in western Thailand. For 14 years I taught courses and seminars on, or including, primate behavior on both the college and university level before focusing my professional activities on the conservation of primates in Asia.

All macaque monkeys, rhesus monkeys included, are social and gregarious primates and highly intelligent. All of their activities including foraging for food (and water) and feeding, which may occupy a good percentage of the day, and social behavior such as grooming and play and sexual behavior, are carried out as members of complex social groups. Having been born and/or raised in captivity would not diminish the biological potential for these behaviors. To isolate and subject monkeys to restraint, such as restraint chair confinement, for any period of time or to deprive them of water (or food) for extended periods of time, such as 22 hours, would be extremely stressful and unethical in my opinion and might well invalidate the results of tests conducted with or on them. In a wild (natural) population of macaques, members of the social group would attempt to help a monkey remove any foreign object, be it animate or inanimate, from its head. To limit or further limit the motion of a monkey by surgically implanting restraining bars in its skull I would think would subject the monkey to extreme stress and discomfort.

Considering our current knowledge of primate intelligence and behavior, one wonders why research institutions would have recourse to the procedures of deprivation mentioned above in experiments involving primates and other animals.

Ardith A. Eudey, Ph.D.
164 Daytor Street
Upland, CA 91786-3120
30 June 2008
March 19, 2008

Mr. Michael Budkie, Executive Director  
Stop Animal Exploitation NOW!  
PMB 280  
1801-B State Route 28  
Milford, OH 45150

Dear Mr. Budkie,

Regarding the primate experiments you brought to my attention, there is no doubt in my mind that the procedures caused the animals great pain and suffering and it is questionable whether the protocols should ever have been approved by the institutional review boards. Specifically, confining primates to restraint chairs and bolting their heads in place is a highly stressful maneuver. Also, withholding water for up to twenty-two hours a day for five days a week in order that the monkeys are motivated to work for fluid reward is unconscionable. Finally, it is my opinion that infecting primates with diseases, like SIV, should be acknowledged as causing pain and suffering in primates unfortunate enough to be selected for this type of infectious disease research.

If it is necessary to use primates in research they should be treated with care and compassion. Their accommodation and social needs should be met, their environments should be enriched. They should have constant access to food and water (except for the shortest period of withholding necessary prior to general anesthesia), and they should receive round-the-clock care. Personally, I do not think they should be used in experiments that cause severe pain and suffering and should preferably not be used in terminal experiments. Any pain that does result from an experimental procedure should be appropriately treated by someone skilled in the art of recognizing the signs of pain in a primate and knowledgeable of when and how to intervene with timely use of sedatives and analgesics.

It is with reluctance that I accept the fact that some primate experimentation may be necessary but I am totally opposed to the callous indifference that I have learned about or seen in some laboratories. Sometimes scientists, who are completely immersed in their own niche area of research using a protocol they have developed over the years, lose sight of the fact that their working with sentient creatures who, at the very least, deserve the benefit of the doubt and the very best care that comes through the recognition and treatment of pain, distress, and suffering.

K millenni

Nicholas H. Dodman, Professor  
Director, Animal Behavior Clinic  
Tufts Cummings School of Veterinary Medicine  
North Grafton, MA

NHD/nt
29 January 2008

Michael A. Budkie, A.H.T.
Executive Director
Stop Animal Exploitation NOW!
PMB 280
1081-B State Route 28
Milford OH 45150

Mr. Budkie:

You have asked me to comment on certain practices in laboratories and the reporting of animals subjected to those practices. As you are aware, I am a veterinarian and Emeritus Professor of Veterinary Medicine at the University of California. I have over 35 years of experience including the use of nonhuman animals in a research setting.

The Animal Welfare Act requires annual reporting of the use of certain nonhuman animals used in research and other activities. The form used for this is "Annual Report of Research Facility" and is filed with the United States Department of Agriculture (USDA). One of the categories includes animals who have been subjected to unrelieved pain or distress. These animals are currently required to be reported in "Column E" of the report with an explanation of why unrelieved pain or distress was permitted.

It is my experience that many animals who should be listed in Column E are not. Below are just some of the conditions to which animals are subjected and who should be, but often are not, reported in Column E.

**Water deprivation** is used to "train" animals such as nonhuman primates in order to make them "perform" in an experiment. This deprivation can be for as long as 22 hours in some cases over a period of many days to weeks. Although the investigator knows that water or other fluids will be provided at some point and the animals will not be allowed to dehydrate, the nonhuman animals do not. For the animals, the witholding of water for such periods is distressing.

**Food deprivation** is also used to "train" animals. Similarly to water deprivation, animals subjected to this should be listed in Column E.

**Restraint chairs** are used for nonhuman primates in certain experiments so that the animals cannot move except in the limited manner consistent with the goals of the experiment. Nonhuman primates, regardless of how long they may have been in captivity, must be considered wild animals. One of the most stressful things that can be done to a wild animal is to restrain her or him. As a result, nonhuman primates have to be "trained" to sit in these chairs because it is unnatural and highly stressful for them

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*a*Number of animals upon which teaching experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in those animals and the reasons such drugs were not used must be attached to this report)*
to be confined in this manner. To make matters even worse for them, head restraining devices may be surgically implanted so that the animal's head will not move at all during a recording session. These recording sessions can be many hours long spanning many days, weeks or months. It is not being anthropomorphic to imagine that being forced to sit in virtually one position, without being able to occasionally move and stretch, results in significant discomfort and should be considered distressful.

Painful diseases such as certain cancers, immunodeficiency virus-induced disease, diseases causing serious dysfunction (such as respiratory distress) and others are induced in nonhuman animals experimentally. In these cases, the animals are usually not treated in order to study the development of the disease. There is little question that animals subjected to these situations should be listed in Column E.

Whereas there may be debate about the propriety of using nonhuman animals in research, the research community should be scrupulously honest about how they are treating the animals they are using. When animals are improperly categorized in the "Annual Report of Research Facility" as to infliction of pain or distress, this raises several questions. Are the investigators unaware of or unconcerned about the negative effects their manipulations have on the animals? Are the investigators trying to minimize the impact on the animals so as not to invite closer scrutiny of their practices? As the regulatory agency involved, the USDA should carefully scrutinize these reports and challenge the reporting agencies about any apparent improprieties.

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To Whom It May Concern:

I am a veterinarian with 46 years experience including 10 years in laboratory animal medicine at the University of California, Berkeley and 10 years of experience dealing with non-human primates.

I have been asked to comment on several procedures which use primates in experimentation, specifically confinement of primates to restraint chairs, use of water and/or food deprivation as a means of coercing primates into participating in experimental procedures, and the attachment of devices to the skulls of non-human primates.

Depriving sentient animals of food or water for extended periods of time is highly stressful. The use of this deprivation to "train" primates to "work" in an experimental procedure causes distress - otherwise, it would be ineffective as a training tool. Experimental procedures that utilize food or water deprivation, for periods as long as 22 consecutive hours, cause distress to primates and are unethical.

The use of restraint chairs in research projects involving non-human primates causes them distress. Despite being raised in captivity, primates retain their natural instincts, such as movement, exploration of surroundings, and escape from frightening situations. Severe restraint or confinement, such as that involving restraint chairs, is one of the most stressful things that can be done to a primate. This kind of restraint often involves a long "training" process. The situation is exacerbated when the motion of a primate is further limited by the use of surgically implanted restraining bars. Experiments that utilize these procedures are unethical.

Any project that involves these research techniques should be considered as falling into the USDA reporting category B, causing more than momentary unalleviated pain and distress. Practices such as these should be eliminated from the research programs of any progressive institution that performs animal experimentation.

[Signature]

Bruce Max Feldmann, DVM
Photograph of Primate Vision Experiment
at the Massachusetts Institute of Technology