United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Eastern Regional Office

Animal Care

920 Main Campus Dr
Suite 200
Raliegh, NC 27606

October 12, 2001

Michael M. E. Johns M.D.
Executive VP for Health Affairs
Emory University
1440 Clifton Road, N. E.
Atlanta, GA 30322

CERTIFIED MAIL
RETURN RECEIPT
7000 1670 0007 1097 2313

RE: 896
57-R-0003
Warning Notice
APHIS Form 7060

Dear Dr. Johns:

The enclosed APHIS Form 7060, "Official Warning, Violation of Federal Regulations," is being issued to you for alleged violations of the Federal Animal Welfare Act. This notice is being issued at this time as a serious warning that if you fail to comply with the requirements of the Animal Welfare Act in the future, this citation and all past and future documented violations will be used to justify a more severe penalty. The Animal Welfare Act provides for penalties of up to $2,750 per violation. If you have any questions regarding this citation or the Animal Welfare Act, please contact this office at the above address or phone (919) 716-5532.

Sincerely,

Elizabeth Goldentyer, D.V.M.
Eastern Regional Director, Animal Care

Enclosure
cc: J. Kinsella, Regional Director, IES
M. Guedron, VMO
G. Gaj, SACS
Facility File

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CASE ... GA01060-AC
GA01061-AC

VIOLATOR
896
57-R-0003
Emory University

ADDRESS *(Street, City, State, Zip Code)*
1440 Clifton Road, NE
Atlanta, GA 30322

OFFICIAL WARNING
VIOLATION OF FEDERAL REGULATIONS

The Department of Agriculture has evidence that on or about **June 11, 2001 and August 10, 2001** you or your organization committed the following violation of Federal Regulations:

9 CFR, SECTION 2.32 (a) — **Failure to ensure employees are adequately trained to perform their duties.**

- **Animal Caretaker failed to notice chain used to secure metabolism cage to wall was not attached. A Rhesus macaque was strangled by the loose chain.**

9 CFR, SECTION 3.80(a)(2)(ii) — **Failure to provide primary enclosures constructed and maintained so that they protect the non-human primates from injury.**

- **The chain used to secure the metabolism cage to the wall was loose and not attached to the wall. A Rhesus macaque was strangled by the loose chain.**
- **The chimpanzee "Sellers" was found dead with his head wedged between the bed board and the back of the metabolism cage wall.**

Titles 7 & 9 Code of Federal Regulations were promulgated to help prevent the spread of animal and plant pests and diseases and assure the humane treatment of animals. Since violations of the regulations can have serious and costly impact detrimental to the public interest, you are warned of this violation. Any further violation of these regulations may result in the assessment of a civil penalty or criminal prosecution. If you have any questions concerning this warning or violation, please contact the listed APHIS Official.

APHIS OFFICIAL *(Name and Title)*
Elizabeth Goldentyer, DVM — **Regional Director**

OFFICE ADDRESS:
920 Main Campus Dr., Suite 200
Raleigh, NC 27606
TELEPHONE NO. AC **(919) 716-5532**

SIGNATURE

DATE ISSUED
10/15/01

FOR PERSONAL SERVICE - RECEIVED BY: *(Name and signature)*

DATE RECEIVED:

FOR CERTIFIED MAIL - RECEIPT NO:
7000 1670 0007 1097 2313

APHIS FORM 7060 (JUN 91) Previous editions may be used

PART 1 - VIOLATOR

FYI
Gj
Gvedman

EMORY UNIVERSITY

Institutional Animal Care and Use Committee

Emory West Campus
1256 Briarcliff Road, Room 421-S
Atlanta, GA 30306
Phone: 404-727-6786
Fax: 404-727-8452

IACUC@emory.edu

September 12, 2001

f a x

TO: Dr. Elizabeth Goldentyre

FROM: (b)(6)
Chair, IACUC

RE: **Response to August 15, 2001, questions regarding Yerkes chimpanzee death, July 25, 2001**

Page 1 of 4

Attached is information in response to specific questions raised in Dr. Potkay's letter of August 15, 2001, which was sent in response to the Emory letter of July 25, 2001, regarding the unexpected death of a chimpanzee at the Yerkes Primate Center.

EMORY UNIVERSITY

Institutional Animal Care and Use Committee

September 12, 2001

Stephen Potkay, VMD
Office for Protection from Research Risks
Division of Compliance Oversight
Office of Laboratory Animal Welfare
6100 Executive Blvd., Suite 3B01
MSC 7507
Rockville, MD 20892-7505
Telephone: (310) 496-7163 ext. 7
Fax: (301) 402-7065

Dear Dr. Potkay:

The following additional information is being provided in response to specific questions/issues raised in your letter of August 15, 2001, sent in response to our letter of July 25, 2001 (with enclosure) regarding the unexpected death of a chimpanzee at the Yerkes Primate Center.

Please clarify whether there were any pathologic findings supporting a diagnosis of suffocation (asphyxiation).

(b)(6) the Board Certified Veterinary Pathologist who conducted the postmortem examination, did not find specific pathological evidence supporting a diagnosis of suffocation. Supporting evidence, for example, might include petechial hemorrhages in the eyes or mouth. Such changes were not seen, although it is possible that they may have been obscured by the deep discoloration of facial and mouth tissues that was observed. In the absence of such findings, the primary cause of death was listed based on circumstances surrounding the animal's death, in particular, the position of the animal at death. Thus, in the absence of evidence clearly implicating other factors, the cause of death was judged to be positional asphyxiation. As noted in the earlier report, it is not possible to rule out as potential contributing factors either myocardial disease (determined at the time of histological evaluation of heart specimens obtained at postmortem, but not detectable prior to that) or the anesthetic episodes.

OLAW requests clarification on .. matters that involve institution-wide policies and procedures applicable to work falling under the PHS umbrella. ... please provide an assessment of:

Emory University
1256 Briarcliff Road
4th Floor, South Wing
Atlanta, Georgia 30306
Tel 404.727.6786
Fax 404.727.8452
E-mail IACUC@emory.edu

1) the nature and frequency of post-procedural monitoring following the administration of anesthetics and the documentation that accompanies such monitoring.

Following any anesthetic episode animals are monitored by trained and experienced individuals to ensure an uneventful recovery. The details of such post-procedure monitoring are dependent on the case specifics, including agent used, dose and frequency of administration, procedures performed, and the age, history and clinical condition of the animal(s). Following administration of dissociative anesthetics (ketamine or Telazol) to healthy animals with no history of anesthetic difficulty, such monitoring would typically be continuous for an initial period while procedures were being performed and immediately following the animal's return to the home or metabolism cage, then at intervals (typically 30-60 minutes) until recovery. No written record of monitoring is kept once the animal is returned to the home or metabolism cage if the recovery proceeds normally. Any indication that the recovery is not proceeding normally is reported immediately to a clinical veterinarian. An assessment is then made by the clinician, and any necessary treatment or intensification of monitoring is ordered. All abnormalities and consequent interventions are recorded.

These procedures were followed in the Sellers case, as documented in the report submitted on July 25, 2001. As noted in that report, there were no indications of problems with recovery during the four-hour period between administration of ketamine (at approximately 2:50 pm) and the final check (just after 7:00 pm) before Sellers was found dead at approximately 8:00 pm.

When gas inhalant anesthetics (isoflurane and oxygen) are delivered, blood pressure, pulse, and respiration are monitored continuously and recorded periodically. After withdrawal of the anesthetic, the animal is similarly monitored until it recovers reflexes and begins to move, at which time it is extubated. The animal is then returned to its home, or metabolism, cage and monitored at appropriate intervals (from continuous to 15-30 minute intervals, depending on case specifics) until recovery. As above, any indication of abnormality would lead to clinical assessment and appropriate intervention by a clinician, with all such incidents recorded.

2) The adequacy, in terms of numbers, of staff to accomplish monitoring

Adequate staff to accomplish post-anesthesia monitoring are available, and no anesthesia episode would be scheduled in the unlikely event that an adequate number of personnel were not on hand on a particular day. At the time of the death of Sellers, more than 40 individuals were employed in positions in which post-anesthetic monitoring would be among the job responsibilities. These include clinical veterinarians, veterinary technicians, animal care supervisors, night staff and research specialists. With regard to the Sellers case, as noted in the report submitted, personnel who were at the Center on the evening of June 11, 2001 specifically to work with Sellers and the second chimpanzee assigned to the protocol included a clinical veterinarian, a veterinary technician, a senior investigator and an animal care supervisor.

3) The use of balanced, inhalant anesthesia versus injectables.

The selection of the appropriate anesthetic is based on professional veterinary judgment. In addition, it should be noted, it is not a choice of injectible dissociative vs. inhalant anesthetic. All anesthetic episodes in this environment begin with an injectible dissociative anesthetic, a step that is necessary to get either monkeys or chimpanzees from a home cage or metabolism cage to the procedure table. Balanced inhalant anesthesia denotes a multiple drug regimen to target the state of consciousness, analgesia, muscle relaxation, and reflexes. The dissociative anesthetics that have been used for many years in nonhuman primate medicine are excellent for restraint and immobilization.

As noted in the original report, dissociative anesthetics are used when access is required for relatively minor procedures, a choice that is based on the safety and efficacy of these anesthetics in extensive use here and elsewhere. Inhalant gas anesthesia is used for procedures such as major surgery and other painful procedures, where dissociative anesthetics would not provide sufficient analgesia. The professional judgment of the experienced clinical veterinarians here was that dissociative anesthetics were the better choice for the procedures conducted on Sellers on the morning of June 11, 2001. With respect to the second access that afternoon, there was no choice given that a dissociative anesthetic was required (see above), and the procedure was relatively minor and quickly accomplished.

Sincerely

(b)(6)

Chair, Emory University IACUC

Cc: Dr. Elizabeth Goldentyer
Dr. Michael Johns
(b)(6)

United States Department of Agriculture

Animal and Plant Health Inspection Service

Animal Care

Eastern Region
2568A Riva Road
Suite 302
Annapolis, MD 21401

Subject: Request for Investigation of Alleged Violations Regarding the AWA, Regulations and/or Standards

To: William T. Grace ~~Robert E. Hogan,~~ Deputy Director
Investigative and Enforcement Services
Eastern Region

Date: 7-26-01

Case No.: _____

Enclosed please find the following documents involving:

License/Registration No.: 57-R-0003

Name: _____

Doing Business As: Yerkes Primate Center

Address: _____

_____

Phone No.: _____

____ APHIS Form 7003	____ APHIS Form 7012	____ Health Certificates
____ APHIS Form 7004	____ APHIS Form 7019	____ Airbills/Ship. Invoices
X APHIS Form 7005	____ APHIS Form 7020	____ Measurements
____ APHIS Form 7006	____ APHIS Form 7020A	____ Sale/Purchase Invoices
____ APHIS Form 7006A	X APHIS Form 7023	____ Photographs
____ APHIS Form 7008	____ APHIS Form 7024	____ Complaints
X APHIS Form 7011	____ Prior Violations	____ Statements/Logs/ Affidavits

OTHER: 1. information letter from IACUC Chair - (b)(6)

2. News Release from Alan Christian

Ellen Magid, D.V.M.
Supervisory Animal Care Specialist
Animal Care - Eastern Region

APHIS—Protecting American Agriculture

United States
Department of
Agriculture

Marketing and
Regulatory
Programs

Animal and Plant Health
Inspection Service

Eastern Regional Office

Animal Care

920 Main Campus Dr.
Suite 200
Raleigh, NC 27606

(b)(6)

November 27, 2001

Dear (b)(6)

This is in response to your concerns regarding the death of the chimpanzee "Sellers" at the Yerkes Regional Primate Research Center located in Atlanta, GA. Our office also received an anonymous "whistle blower" complaint concerning this matter.

We have concluded our investigation and we found Sellers was adequately monitored during recovery from the anesthesia, the medical history and physical evaluation of the animal was adequate to determine if there were any preexisting conditions. We also found there were adequate numbers of personnel available to care for the animals and the personnel had adequate training and experience to perform their duties.

Sellers was frequently observed throughout the recovery period. He had recovered sufficiently to climb more than three feet vertically to the bed board. By 7:05 PM, the recovery appeared normal and uneventful. At 8:00 PM, Sellers was found with his head wedged between the cage wall and the bed board.

We have concluded the unfortunate death of Sellers was due to the construction design of the metabolism cage. The enclosure has been subsequently modified to reposition the bed board closer to the cage wall.

Our office issued an APHIS Form 7060, "Official Warning, Violation of Federal Regulations" to Emory University. The University failed to provide an enclosure constructed and maintained so that it protects the non-human primates from injury. Please be assured we will continue to monitor the facility for compliance with the AWA take appropriate enforcement action if violations are found.

Thank you for your concern for the welfare of animals.

Sincerely,

Elizabeth Goldentyer, D.V.M.
Regional Director
Animal Care - Eastern Region

cc: 57-R-0003
M. Guedron, VMO
G. Gaj, SACS
Correspondence

USDA, APHIS, ANIMAL CARE
COMPLAINT/SEARCH

COMPLAINT/SEARCH NO:__01-204___ REPLY DUE: ____8/15/01_____

RECEIVED BY:	DATE:	REFERRED TO:
Goldentyer	6/28/01	Guedron

ESTABLISHMENT NAME	COMPLAINANT NAME
Yerkes Regional Primate Center	Anon (b)(6)
PERSON CONTACTED	ORGANIZATION
LICENSE/REGISTRATION NO.	REPLY REQUESTED? YES ____ NO x___
ADDRESS	ADDRESS
CITY, STATE, ZIP CODE	CITY, STATE, ZIP CODE
PHONE NUMBER	PHONE NUMBER

DETAILS OF THE COMPLAINT/SEARCH:
Please check out the death of Chimp "Sellers" as per the attached complaint.

ACTION TAKEN BY INSPECTOR:
(SEARCHES: APPLICATION PACKET PROVIDED? YES _____ NO _____)

VALIDITY OF COMPLAINT/SEARCH (CIRCLE ONE)
3 = All issues were confirmed and are valid noncompliances (valid searches)
2 = Some issues were confirmed and are valid noncompliances
1 = None of the issues were confirmed and/or none represent noncompliances (invalid searches)

INSPECTOR: _____ DATE _____

REVIEWED BY: _____ DATE _____

USDA/APHIS/AC
920 Main Campus Drive, Suite 200
Unit 3040
Raleigh, NC 27606

JUN 25 2001

To Whom It May Concern:

Please investigate the recent death of a chimpanzee named Sellers at the Yerkes Regional Primate Research Center in Atlanta, GA. I hope that the Center has contacted you themselves about the death of this chimpanzee, but given the possible circumstances surrounding his death, I felt it necessary to ensure that the USDA be aware of Sellers' death.

Unfortunately, I have no direct knowledge of the circumstances surrounding Sellers' death. However, I have reason to believe that his death occured following anesthesia, and that Sellers was left unattended, and not properly observed, as he recovered from anesthesia. Had the chimpanzee been observed until fully awake, his death may have been avoided.

I urge the USDA to identify and interview all individuals who were responsible for the care and monitoring of Sellers on the day that he died, and determine if his death was indeed the result of negligence. It is my hope that this is not the case, but I feel that the USDA rather than internal Yerkes personell should make that determination.

I must register my concerns anonymously. I have no wish to lose my job, and I fear repercussions should I reveal my identity. I hope that this in no way prevents the USDA from looking into this matter.

Sincerely,
A Concerned YRPRC Staff Member

(b)(6)

July 11, 2001
VIA FAX (5 pages)

Dr. Elizabeth Goldentyer
Director, USDA Eastern Sector
920 Main Campus Drive
Suite 200
Raleigh, NC 27606
919-716-5532 (phone)
919-716-5696 (FAX)

Dear Dr. Goldentyer:

Please consider this a formal complaint against the Yerkes Regional Primate Research Center in Atlanta filed by (b)(6) an international animal advocacy and rescue organization based in (b)(6)

We have been informed by whistleblowers that a young chimpanzee named Sellers died at Yerkes last month. We believe that if the circumstances of this death as relayed to us by the whistleblowers are confirmed, then Yerkes would clearly be guilty of negligence and multiple violations of the Animal Welfare Act and the PHS Policy for the Humane Care and Use of Laboratory Animals which resulted in his death. We base this opinion in large part on consultations with veterinarians having over 50 years of combined clinical chimpanzee experience as well as our own research of the medical literature.

THE CIRCUMSTANCES ALLEGED

The whistleblowers state that Sellers, who was less than 20 years old and weighed approximately 170 pounds, had been in an experiment for testing a drug for the treatment of gout (b)(6) will not comment on this, other than to point out that in 6,409 references for "gout" in the published medical literature (Medline, searched at http://www.ncbi.nlm.nih.gov/PubMed/), we could find only one experiment with chimpanzees – the testing of a gout drug published in 1993 and performed by toxicologists (b)(6) at the Coulston Foundation in Alamogordo, New Mexico.

The whistleblowers allege that Sellers was anesthetized with the commonly used injectable anesthetics Telazol and/or ketamine sometime in the morning, and that he was kept "under" for at least two hours with multiple supplemental doses. Several hours later, sometime in the afternoon, Yerkes again "knocked down" Sellers.

Several hours after this latest knockdown, Sellers was found dead in his cage, with his head wedged between the bedboard and the inner surface of the cage wall. **Tellingly, the whistleblowers state that Yerkes did not know when he died, and could only approximate his time of death within a two-hour time span**. This raises myriad questions regarding egregiously inadequate post-anesthetic monitoring, which we will analyze in this complaint.

The whistleblowers also allege that Sellers had some kind of heart or circulatory condition, and that Yerkes is claiming that his death was anesthesia-related.

ANALYSIS

1. Inadequate Monitoring

The highly experienced chimpanzee clinicians consulted by (b)(6) were unanimously appalled by the allegation that Yerkes did not know when Sellers died, and could only approximate his time of death within what one veterinarian termed an "unbelievable" two-hour time span. These veterinarians all believed that this indicated egregiously negligent post-anesthetic monitoring, especially in light of the multiple doses, and type, of anesthetic used as well as Sellers' pre-existing condition. The medical literature supports this viewpoint unequivocally; such circumstances would clearly be in violation of basic, accepted standards of veterinary practice.

According to the widely used reference manual *Essentials for Animal Research: A Primer for Research Personnel*, published by the USDA's Animal Welfare Information Center, National Agricultural Library (Second Edition, 1994, available at http://www.nalusda.gov/awic/pubs/noawicpubs/essentia.htm):

*"Pay particular attention to post-anesthetic care. The anesthetist's responsibility does not end when the animal is taken off the table....**Be sure the animal is protected from injury, either self-inflicted or by other animals, during recovery**"* (quoted from Chapter 4, "Principles of Anesthesia and Analgesia," emphasis added)

Considering the allegation that Sellers had been given multiple doses of the injectable anesthetic Telazol and/or ketamine, had been "under" for hours, and had been anesthetized again later in the day, how could Yerkes' failure even to know when he died – let alone being able to estimate only within an "unbelievable" two-hour span – possibly not constitute grave violations of the Animal Welfare Act, PHS Policy and basic, accepted standards of veterinary medicine?

Indeed, the USDA has filed formal charges against the Coulston Foundation for just such an egregious failure to provide post-procedural monitoring in accordance with standard, accepted veterinary practice. The agency's March 19, 1998 formal charges stated that Coulston had "fail[ed] to provide adequate post-procedural care in accordance with current established veterinary medical and nursing procedures" by "fail[ing] to adequately monitor the chimpanzee [Echo, who died] following surgery." Such established veterinary medical and nursing procedures clearly also include adequate post-anesthetic monitoring, in addition to post-surgical monitoring.

Moreover, how could Yerkes have allowed Sellers to recover in a cage where he could put himself in the position of asphyxiating himself between the bedboard and the cage wall without the strict post-procedural monitoring mandated by accepted standards of established veterinary practice – especially if he had been groggy and/or not fully recovered from the anesthesia, and thus **not** "protected from injury, either self-inflicted....during [anesthetic] recovery?"

In addition, the veterinarians consulted by (b)(6) also indicated that multiple doses of the kind of anesthetic used on Sellers could become "cumulative" in the body. The multiple, supplemental doses, and potentially the amount of time he was "under," could make recovery time longer, thus mandating even more that he be monitored closely during the prolonged recovery period. This, too, is confirmed by the literature. According to "Guidelines for the Use of Anesthetics, Analgesics and Tranquilizers in Laboratory Animals," published by the University of Minnesota and available at http://www.ahc.umn.edu/rar/anesthesia.html :

"Recovery time can be prolonged if animals were under for a long time or if injectable agents were used."

This would be even more problematic if Sellers was overweight. The veterinarians consulted by (b)(6) raised questions about Sellers' alleged weight of 170 pounds. Without knowing his clinical picture, it is of course impossible to say whether or not he was overweight, but his sheer size did raise some questions with these veterinarians. One veterinarian who has over 20 years of clinical chimpanzee experience said he had never treated a chimpanzee who weighed 170 pounds, and expressed surprise when informed of Sellers' weight and age (less than 20 years old). Multiple doses of the anesthetics used on Sellers could also make recovery that much longer if he was overweight. As *Essentials for Animal Research: A Primer for Research Personnel* notes:

"Fat can later serve as a repository for the [anesthetic] agent, thus prolonging recovery."

As the University of Minnesota's "Guidelines for the Use of Anesthetics, Analgesics and Tranquilizers in Laboratory Animals" states:

"...most anesthetics share this problem [overdosing and prolonged anesthetic recoveries] when administered to obese animals."

The allegation that Yerkes did not know when this chimpanzee who had just undergone multiple doses of anesthesia, and could only approximate his time of death within an "unbelievable" two-hour time span, clearly indicates that Yerkes violated one of the most basic precepts of accepted, standard veterinary practice: to make sure an animal is fully recovered from anesthesia by monitoring him or her intensively. This appalling negligence is even more egregious when one takes into account the duration and type of anesthesia as well as Sellers' pre-existing condition.

2. Pre-Existing Condition(s)

According to the veterinarians with over 50 years of clinical chimpanzee experience, Sellers' health status would have played a key role in not only his recovery from anesthesia, but also Yerkes decision to perform this experiment on him in the first place.

If Sellers was overweight, that would have greatly increased the risk of anesthesia and recovery. The whistleblowers allege that Sellers suffered from some kind of heart or circulatory condition. These condition(s) would constitute a greater risk for both anesthesia and recovery – and would mandate that much more the strict post-anesthetic monitoring that Yerkes clearly and egregiously failed to perform.

This, too, is confirmed by the literature. As *Essentials for Animal Research: A Primer for Research Personnel* states:

"The presence of pre-existing disease will increase an animal's anesthetic risk....Pay particular attention to the health of the animal before using it [sic] in an experiment. A preanesthetic checkup is a good idea. To minimize anesthetic risks, only use healthy animals...."

Why did Yerkes choose Sellers – a chimpanzee who allegedly had a heart or circulatory condition, and may have been overweight – for an experiment that mandated multiple anesthetic doses and hours under anesthesia? Did Yerkes bother to perform the "preanesthetic checkup" referenced in the widely used, widely accepted *Essentials for Animal Research: A Primer for Research Personnel* – a USDA publication? If not, why not? If so, why did they proceed with this dangerous protocol if he had these pre-existing condition(s)? According to the whistleblowers, Yerkes is claiming that his death was anesthesia-related. Had Yerkes previously administered to Sellers the same types of anesthesia used here? Did they use the same dosages, with multiple supplements? Did Yerkes keep him "under" for similar extended periods of time? Why did they clearly not monitor him closely post-anesthetically, despite these pre-existing condition(s) and the basic precept of accepted, established veterinary practice that all animals – let alone ones with pre-existing condition(s) and an apparently prolonged recovery period – must be closely monitored?

3. Does Yerkes Have Adequate Personnel as Mandated by the Animal Welfare Act?

Why did Yerkes fail so egregiously to adequately monitor Sellers post-anesthetically? Does this appallingly inadequate post-anesthetic monitoring indicate that Yerkes does not have the personnel – in both numbers and training – required by the Animal Welfare Act to provide the adequate care mandated by accepted, standard veterinary practice? As section 3.85 of the Act's regulations states:

"Every person subject to the Animal Welfare [Act] regulations...maintaining nonhuman primates must have enough employees to carry out the level of husbandry practices and care required [by these regulations]. The employees who provide husbandry practices and care, or handle nonhuman primates, must be trained and supervised by an individual who has the knowledge, background, and experience in proper husbandry and care of nonhuman primates to supervise others. The employer must be certain that the supervisor can perform to these standards."

How many people were responsible for monitoring Sellers post-anesthetically? How many other animals were these individual(s) responsible for monitoring during that same time? Did a lack of personnel – either too few employees, or employees not adequately trained – make it impossible to adequately monitor Sellers as mandated by the Animal Welfare Act, the PHS Policy and basic, accepted standards of established veterinary practice? How could Yerkes not have performed something so basic and fundamental to accepted veterinary standards as closely monitoring a chimpanzee who had just undergone multiple doses of anesthesia and had been "under" for hours?

CONCLUSION

If the allegation is true that Yerkes did not even know when Sellers died, and could only estimate his time of death within an "unbelievable" two-hour time span, then (b)(6) believes that it is clear beyond any doubt that Sellers' death was caused by gross negligence and violations of the Animal Welfare Act and the PHS Policy committed by Yerkes. The other information supplied by the whistleblowers only confirms this view, and indicates appalling negligence and violations of the most basic precepts of accepted, standard veterinary medical and nursing practice. Yerkes must not be allowed to violate with impunity these basic precepts of both accepted veterinary practice and federal animal welfare laws. The lives of thousands of primates at Yerkes hang in the balance. To the best of (b)(6) knowledge, Yerkes is one of only two registered research facilities with chimpanzees that have been fined by the USDA for violations of the Animal Welfare Act related to negligent primate deaths. Your agency must act to enforce the law and ensure that Yerkes' egregious negligence – which appears to be a pattern – does not go unpunished.

Sincerely,

(b)(6)

DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office for Protection from Research Risks
Division of Animal Welfare
6100 Executive Boulevard, Suite 3B01
MSC 7507
Rockville, Maryland 20892-7507
Home Page: http://grants.nih.gov/grants/oprr/oprr.htm

FOR EXPRESS MAIL:
Office for Protection from Research Risks
Division of Animal Welfare
6100 Executive Boulevard, Suite 3B01
Rockville, Maryland 20852
Telephone: (301) 496-7163 ext 7
Facsimile: (301) 402-7065

August 15, 2001

Re: Animal Welfare Assurance
#A3180-01

(b)(6)
Chair, Animal Care and Use Committee
Department of Ophthalmology
Winship Cancer Center
Emory University
Atlanta, GA 30322

Dear Dr. Kapp:

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 25, 2001 letter, with enclosure, notifying this Office of the unexpected death of a chimpanzee (Sellers) at the Emory University's (EU) Yerkes Regional Primate Research Center (Yerkes) on June 11, 2001.

Based on its assessment of the detailed information provided with your letter, this Office understands that Sellers was a was a healthy, 17 year old, non-obese chimpanzee (76.5 kg) which was being used in an EU Animal Care and Use Committee (ACUC) reviewed and approved study. We further understand that he died following the conclusion of a procedure associated with the study which required anesthetization (tiletamine-benzodiazepine-ketamine) for the administration of an experimental drug and the collection of blood and urine samples over a two hour period in the morning and again, using ketamine alone, in the afternoon for collection of the final samples. This Office recognizes that the animal was up and moving about four hours and 20 minutes after the last dose of anesthetic (ketamine) at 10:30 am. Likewise, we understand that the chimpanzee had recovered sufficiently to climb more than three feet vertically to the resting board within 3 hours and 40 minutes of the time the anesthetic was administered in the afternoon and that he was found dead about an hour later, with his head between the resting board and the cage wall. We recognize that the anesthetic regimen used in this study, and on numerous other occasions at the EU, is not unique to your institution.

OLAW acknowledges that the diplomate of the American College of Veterinary Pathology who performed the necropsy was unable, in the absence of significant gross or histologic pathology, to provide a definitive cause of death. In this respect, we recognize EU's theories that factors contributing to the death may have included airway obstruction or respiratory arrest due to position, residual

anesthetic effects, or cardiac arrhythmia. Please clarify whether there were any pathologic findings supporting a diagnosis of suffocation (asphyxiation).

This Office understands that, in the event that cage design was a factor in this animal's death and although there has never been an incident of this nature during the 15 years that the metabolism cages have been in use, modifications to one metabolism cage—to reduce the gap between the resting board and back wall—were made and are being evaluated prior to implementing similar changes in the remaining cages.

While the particular study in which this unfortunate incident occurred was not PHS-supported, OLAW requests clarification on two matters that involve institution-wide policies and procedures applicable to work falling under the PHS umbrella. In this regard, please provide an assessment, in this case, of:

1. the nature and frequency of post-procedural monitoring following the administration of anesthetics and the documentation that accompanies such monitoring,
2. the adequacy, in terms of numbers, of staff to accomplish monitoring, and
3. the use of balanced, inhalant anesthesia *versus* injectables.

OLAW appreciates having received the EU report on this incident and looks forward to receiving clarifications regarding the items indicated above, and any other comments the EU may have. A written response is requested by **September 14, 2001**.

Sincerely,

Stephen Potkay, V.MD.
Division of Compliance Oversight
Office of Laboratory Animal Welfare

Enclosure

cc: Dr. Elizabeth Goldentyer
[redacted]