



January 7, 2010, 2009

(b) (6)

United States
Department of
Agriculture

Marketing and
Regulatory
Programs

Animal and Plant
Health Inspection
Service

Animal Care

920 Main Campus Drive
Suite 200
Raleigh, NC 27606

Tel No. 919-855-7100
Fax No. 919-855-7123

Vanderbilt University Medical Center
1161 21st Avenue South
D-3300 Medical Center North
Nashville, TN 37232-2104

Dear (b) (6)

Our office has received your January 6, 2010 faxed letter requesting an extension of time to perform the final procedure of the approved multiple major survival procedures granted on September 14, 2009.

The time period granted to complete the approved surgeries was stated to be from September 14, 2009 to December 31, 2009 in the approval letter dated September 14, 2009.

From your letter, it is USDA's understanding that the timing of the final surgery after the approved date range is critical to the scientific goals of the study.

Your request for this extension of time has been discussed with your inspector, Dr. Susanne Brunkhorst, and is hereby approved until January 31, 2010 to complete the final procedures that were approved on September 14, 2009.

Please be advised this extension of time is to complete the multiple major survival procedures that have been previously approved. No additional major survival surgeries may be performed unless prior approval from APHIS is requested and granted as per 9 CFR § 2.31 (c).

If there are further questions or clarifications needed, please feel free to call my office at (919) -855-7101.

Sincerely,

Nicolette Petervary, VMD
Regional Animal Care Specialist
Eastern Region, Animal Care

CC: Dr. Elizabeth Goldentyer, RD
Dr. Susanne Brunkhorst, VMO



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(b) (6)

63-R-0005
File



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FILE

63-R-21105
958

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SEP 2 1 2009

SEP 15 2009

United States
Department of
Agriculture

Animal and Plant
Health Inspection
Service

4700 River Road
Riverdale, MD
20757

(b) (6)

Vanderbilt University School of Medicine
CCC-3322 Medical Center North
Nashville, TN 37232-2103

(b) (6)

Your request for an exemption under 9 CFR, Section 2.31(d)(1)(x)(C) to perform multiple major operative survival procedures on three (3) dogs (*Canis familiaris*) is approved for the period from September 14, 2009, to December 31, 2009. The information detailed in your letter of July 30, 2009, and in the IACUC-approved protocol M/09/120 must be followed. Any deviations will invalidate this approval.

In addition, the following requirements must be met:

1. All animals must be permanently identified prior to or at the time of the next surgery. Tattoos must be legible; a scanner device must be readily available to the USDA-APHIS representative if microchipping is utilized.
2. No more than three additional major operative procedures (two survival surgeries and one terminal surgery) may be conducted per animal.
3. Complete health and surgical records must be maintained on each animal (See Animal Care Policy #3, dated July 17, 2007. Copy enclosed). These records must include the name of any medication administered, as well as the dose, route and time of administration. Appropriate perioperative analgesia must be provided to the animals as directed by your attending veterinarian.
4. Periodic IACUC evaluations of this exemption are required. These evaluations must include an assessment of the animals as well as the effectiveness and soundness of the methods and procedures used on them. Particular attention should be paid to the procedures used to minimize pain and distress. This information must be included in the IACUC reports required under Section 2.35(a).
5. This exemption must be included on the research facility's Annual Report (APHIS Form 7023).



Safeguarding American Agriculture

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Federal Relay Service
(Voice/TTY/ASCII/Spanish)
1-800-877-8339



October 22, 2009

(b) (6)

United States
Department of
Agriculture

Marketing and
Regulatory
Programs

Animal and Plant
Health Inspection
Services

Animal Care

920 Main Campus Drive
Suite 200
Raleigh, NC 27606

Tel No. 919-855-7100
Fax No. 919-855-7123

Vanderbilt University Medical Center
1161 21st Avenue South
D-3300 Medical Center North
Nashville, TN 37232-2104

(b) (6)

Thank you for your letter of October 8, 2009 requesting clarification to the approval for multiple major survival procedures granted on September 15, 2009.

Regarding the approval of an additional three laparoscopic biopsies for the three dogs from a previous study: the third approved laparoscopic biopsy need not be a terminal procedure. The animals may be recovered and continue to be used in the study. However, no additional major survival surgeries may be performed unless prior approval from APHIS is requested and granted as per 9 CFR § 2.31 (c).

Regarding the scenario presented in your letter if funding for the current protocol is continued, and an additional laparoscopy is required: as above, no additional major survival surgeries may be performed unless prior approval from APHIS is requested and granted as per 9 CFR § 2.31 (c). However, a non-survival major operative procedure would be considered permissible.

Regarding the scenario presented where the current study is discontinued: The animals may be transferred back to the original protocol. Once again, however, no additional major survival procedures may be performed unless prior approval from APHIS is requested and granted as per 9 CFR § 2.31 (c).

To clarify the timeline in the September 15 approval letter for multiple major survival surgeries in the three dogs: the end-date of December 31, 2009 for the approval period is for the approved surgeries, not for use of the animals in the study. The animals may be recovered and continue to be used in the study. However, no additional major survival surgeries may be performed unless prior approval from APHIS is requested and granted as per 9 CFR § 2.31 (c).

I hope this response answers your questions. If there are further questions or clarifications needed, please feel free to call my office at (919) -855-7101.



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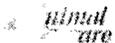
Sincerely,



Nicolette Petervary, VMD
Regional Animal Care Specialist
Eastern Region, Animal Care

CC:

Dr. Elizabeth Goldentyer, RD
Dr. Susanne Brunkhorst, VMO
Dr. Rick Kirsten, SACS
Mr. Joe Nelson, Program Manager
63-R-0005
File



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JAN 27 2009

VANDERBILT  UNIVERSITY

Office of the Chancellor

MEMORANDUM

Date: January 12, 2009

To: (b) (6)

From: (b)(6)

Re: Delegation of Authority of Institutional Official, Vanderbilt University

As Chancellor of Vanderbilt University, I delegate to you the authority of Institutional Official for the Vanderbilt University Animal Care and Use Program. This university program must operate with clear lines of authority and responsibility, a properly functioning Institutional Animal Care and Use Committee (IACUC), procedures for self monitoring, adequate veterinary care, adequate animal care and use training programs, a program of occupational health and safety, an animal facility disaster plan, sound animal husbandry practices, and appropriate maintenance of facilities for housing animals.

In your role as the Vanderbilt University Institutional Official, and if and when applicable,

- 1.) You are authorized to sign the Vanderbilt University PHS Animal Welfare Assurance, making a commitment on behalf of the university that the requirements of PHS Policy on Humane Care and Use of Laboratory Animals will be met;
- 2.) You are authorized on behalf of Vanderbilt University to legally commit that the requirements of the Animal Welfare Act as set forth under the regulations and Standards in the Code of Federal Regulations of 9 CFR parts 1, 2, and 3 of the Animal Welfare Regulations will be met; to sign the USDA research facility registration application and subsequent USDA annual reports for Vanderbilt University;
- 3.) You are authorized with direct oversight of and with the authority to administer the Institutional Animal Care and Use Program;
- 4.) You are authorized to appoint an Institutional Animal Care and Use Committee (IACUC), whose members are qualified through experience and expertise to assess the institution animal program, facilities, and procedures;
- 5.) You are authorized to give full support to IACUC, to maintain a direct line of communication with the IACUC; coordinate with administration, the IACUC, investigators and animal resources to ensure a clearly defined chain of authority; and to act upon any and all IACUC recommendations regarding any aspect of the research facility's animal program, facilities, or personnel training;
- 6.) On behalf of the research facility, you are authorized to ensure that the Attending Veterinarian has sufficient and appropriate authority to ensure that adequate veterinary care is provided at all times and

211 Kirkland Hall
Nashville, Tennessee 37240

tel 615.422.1813
fax 615.322.6060
www.vanderbilt.edu/chancellor

that he or she is able to oversee the adequacy of all aspects of animal care and use for all animals; the attending veterinarian is a voting member of the IACUC; and the Attending Veterinarian is authorized with direct or delegated responsibility for the animals at the research facility;

- 7.) On behalf of the research facility, you are authorized to ensure (through the IACUC, if suitable) that all animal care and use personnel, as well as IACUC members, are qualified to fulfill their responsibilities; and that this responsibility will be met in part through the provision of training and instruction and the review of personnel qualifications with sufficient frequency to fulfill the research facility's responsibilities;
- 8.) You will be kept informed through the IACUC of the extent to which the Vanderbilt University Animal Care and Use Program complies with the PHS Policy on Humane Care and Use of Laboratory Animals, the Vanderbilt University PHS Animal Welfare Assurance, the *Guide to the Care and Use of Laboratory Animals (Guide)*; and, the Animal Welfare Act, all corresponding USDA Animal Welfare Regulations and Animal Care Policies; and all other applicable federal, state and local animal welfare laws and regulations;
- 9.) At a minimum, you will receive semi-annual program evaluation reports from the IACUC describing its program reviews and inspection findings and recommendations regarding any aspect of the research facility's animal program, facilities, or personnel training. These reports will contain a description of the nature and extent of the university's adherence to the PHS Policy, other applicable federal animal welfare requirements and *Guide* recommendations including all identified departures or deviations. Identified departures or deviations will be categorized as significant (i.e. posing immediate jeopardy to animal well-being) or minor, and the reasons for each departure or deviation along with a plan and schedule for corrective action will be established. If failure to meet this plan and schedule results in an uncorrected significant deficiency, the failure will be promptly reported in writing to OLAW and if applicable, to APHIS within 15 days, and to any federal agency funding that activity;
- 10.) In the event of an IACUC suspension of any animal activity, any serious or continuing noncompliance with PHS Policy or other applicable laws and regulations; or any serious deviation from the provisions of the *Guide*, you are authorized, in consultation with the IACUC, to review the reasons for suspension, take appropriate corrective action, and promptly report that action with a full explanation to OLAW and if applicable, to APHIS within 15 days, and to any federal agency funding that activity;
- 11.) If appropriate, you and other officials may conduct further review of IACUC-reviewed animal care and use activities, however, you and other facility officials are NOT authorized to approve an activity involving the care and use of animals that has not been approved by the IACUC.

Your efforts, commitment and expertise on all matters related to the Vanderbilt University Animal Care and Use Program are greatly appreciated.



Vanderbilt University Medical Center

Office of Animal Welfare Assurance

Vanderbilt University
Office of Animal Welfare Assurance
Mimi Eckhard
S-4322 MCN
Nashville, TN 37232-2112
615-343-3591

S-4322 Medical Center North
1161 21st Avenue South
Nashville, Tennessee 37232-2112
phone (615) 936-8163
fax (615) 936-8160

OCT 27 2008

USDA
920 Main Campus Drive
Suite 200, Unit 3040
Raleigh, NC 27606
919-855-7101

October 21, 2008

Dear Sir or Madam:

Please be advised that while our Institutional Official at Vanderbilt University remains (b) (6) [redacted] Vanderbilt University School of Medicine.

I didn't want there to be any confusion on the APHIS Form 7011, which is attached for our 3-year registration.

Please do not hesitate to contact me directly at (b) (6) [redacted] if you have any questions.

Sincerely,

(b) (6) [redacted]

Vanderbilt University



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AUG 11 2009

USDA, APHIS, Animal Care



BY: ANIMAL WELFARE COMPLAINT

Complaint No. E09-219 PETA	Date Entered 29 JULY 09	Received By M. VITACCO
Referred To Dr. Kristen/ Dr. Brunkhorst	Reply Due 30 AUGUST 09	

Facility or Person Complaint Filed Against

Name VANDERBILT UNIVERSITY	Customer/License/Registration No. 858 / 63-R-0005		
Address AA-6206 MEDICAL CENTER NORTH			
City NASHVILLE	State TN	Zip 37222	Phone No 6153222231

Complainant

(b) (6)	Organization PETA		
Address 501 Front Street			
City Norfolk	State VA	Zip 22202	(b) (6)

How was complaint received? email

Forward response to FOIA: Yes No

Details of Complaint: A veterinary technician whose partner worked as an animal care technician (level 3) inside Vanderbilt's laboratories recently contacted PETA with the following information:

- All of the primates kept in Vanderbilt's Wilson Hall "appear depressed."
- During a training exercise, a technician picked up dogs who weighed between 25 and 35 pounds—and had recently undergone invasive abdominal surgery—by grasping the skin on the scruff of the dog's neck without providing any other support.
- A colony of kittens in Vanderbilt's laboratories is being raised in complete darkness. It is unclear whether the absence of light is part of an experimental protocol or whether the deprivation is simply the result of thoughtlessness on the part of animal care staff.

Please see attached email for further details.

Results:

- 1) The non-human primates were inspected. No depression noted. Environmental enrichment plan was reviewed and is excellent and logs indicate that enrichment is provided as indicated in the plan.
- 2) A caretaker was reported to have picked up a dog using the skin at the back of the neck and over the lower back. This was verified via conversations. The incident described did not occur as part of a formal training exercise. The SOP on dog handling was reviewed and is appropriate. Training provided by the facility on this SOP is documented and appears appropriate. Facility was cited for 2.38(f)(1).
- 3) The absence of light for some cats is part of an IACUC approved experimental protocol.
- 4) The IACUC was informed of the whistleblower's complaint on the day it was received by facility personnel. A subcommittee was formed and began its investigation two days later. The subcommittee completed a full investigation of all alleged incidents in the complaint and reported its findings to the entire IACUC at a meeting two weeks later.

Application packet provided? Yes No

INSPECTOR

Susanne Brunkhorst, VMO

DATE

5-Aug-09

REVIEWED BY

Peter R. Kirsten DVM, SACS

DATE

5-Aug-09

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AUG 11 2009

BY: _____



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AUG 11 2009

BY: _____

MEMO

From the desk of Susanne Brunkhorst, VMO

United States
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Health Inspection
Services

Animal Care

920 Main Campus Drive
Suite 200
Raleigh, NC 27606

Tel No. 919-855-7100
Fax No. 919-855-7123

To: Dr. Rick Kirsten
Re: Vanderbilt Complaint ER09-219
Date: Aug 5, 2009

I spent yesterday Tuesday 8-4-09 at Vanderbilt University to investigate Complaint ER09-218 filed by PETA on behalf of an unnamed whistleblower who was the boyfriend of a newly hired Vanderbilt veterinary technician.

I inspected all non-human primates, all dogs, and the cats housed in the dark. I talked to the Director of the Office of Animal Welfare Assurance, the Attending Veterinarian/Director of Division of Animal Care, the Assistant Director of Division of Animal Care/veterinarian, the Facility Manager for the facility where the dogs are housed, the veterinary technician who is the girlfriend of the whistleblower, and the University Manager of Compliance (a lawyer who is a non-voting member of the IACUC).

Records reviewed included the IACUC Complaint Log, the Report of the subcommittee investigating the complaint, the draft copy of the July 22, 2009 IACUC Meeting Minutes, the NHP Environmental Enrichment Plan, the environmental enrichment logs, the SOP on Dog Handling, training records on the Dog SOP, protocol M/06/375 (dark reared cats), Meeting Minutes 12/08 (where this protocol was last approved) and Annual Report FY 2007/2008.

This case deals with sensitive human resources issues and the human resources department had also been consulted. The former girlfriend of the whistleblower apparently took the job at Vanderbilt against the wishes of her boyfriend/whistleblower. This now ex-boyfriend/whistleblower is apparently from what I was told waging



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this campaign to get the girlfriend fired. He is also apparently stalking her and leaving objects on her car. The reason the Vanderbilt Police became involved was because the girlfriend filed a complaint re stalking against him with the police department. Since Vanderbilt is private property, the police apparently called the ex-boyfriend and told him to stay off Vanderbilt property in order to protect the girlfriend/Vanderbilt employee. This information was told to me by the University Manager of Compliance (UMC).

PETA Complaint # 1: All primates kept in Vanderbilt's Wilson Hall appear to be depressed and Vanderbilt either lacks an adequate plan for environmental enhancement or is failing to effectively administer the plan on a large scale.

The whistleblower apparently stated that his girlfriend told him that all the monkeys in Wilson Hall appear depressed. The investigation revealed that the girlfriend never even entered Wilson Hall which is a very secure area that she does not have access to. There are a few monkeys kept in the main animal facility and the girlfriend apparently saw one of these in the imaging center for about 30 seconds as she was walked through it for orientation. I looked at all the monkeys in both the main facility and Wilson Hall. All looked fine. I reviewed the comprehensive 34 page Environmental Enrichment plan and reviewed enrichment logs. I also checked the cages for enrichment items. The enrichment plan appears to be adequate and appears to be followed by staff. Vanderbilt has a full time environmental enrichment coordinator who oversees the program and is very involved in the primate care.

PETA Complaint #2: A laboratory instructor picked up a dog by the scruff of its neck in a training session and the individuals being trained were deprived of proper guidance on acceptable methods of handling dogs.

The girlfriend described to me how the dog was picked up-one hand on skin of dorsal neck and one hand on skin over lower back. The dog had an abdominal incision. The dog did not cry or exhibit any sign of pain. No apparent distress or injury was noted. The caretaker who picked up the dog this way was not an instructor or trainer. The girlfriend and another new employee were spending time with the dogs to learn what went on their housing area in case they ever were

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BY: _____



called in to work with the dogs on the weekend (both had primary responsibility with other species). It was during this time they saw the dog picked up this way. Both individuals had been previously trained on Vanderbilt's SOP on dog handling and knew that this method was incorrect. They asked the caretaker about it and he apparently told them this was an alternative method. Neither woman reported the incident to their supervisors (Vanderbilt's "culture of fear"—I spent some time talking to the AV and the assistant director DAC about this again and they are working on it. I think they now see what we have been telling them about the "culture of fear" that exists at Vanderbilt. They are setting up training on reporting incidents and I suggested they get human resources involved to go over performance reviews and HR issues so employees can understand that if something gets reported they don't automatically get fired although it appears that way from past Vanderbilt actions). I reviewed the SOP for Dog Handling and the training records. The SOP shows appropriate ways to pick up and restrain dogs. The training records show that the male caretaker who picked up the dog incorrectly had been trained on the SOP and the correct way to pick up dogs. This individual was fired. Apparently this individual had had previous problems and was already in a performance improvement counseling program (due to attendance, punctuality and other non-animal issues).

The facility was cited for 2.38(f)(1).

PETA Complaint #3: It is unclear whether the kittens who were observed living in constant darkness were enrolled in a protocol that required that the kittens be deprived of light.

There are currently no kittens living in the dark. There are 7 adult cats living in complete darkness and most of these were raised from kittenhood in the dark. They are part of an IACUC approved protocol. I verified that the protocol had been approved by the full IACUC and that the exception was reported on Vanderbilt's Annual Report.

PETA Complaint #4: It appears that the IACUC was either not informed of the whistleblower's complaint or may not have taken the allegations seriously. In permitting a phone call to be placed from the Vanderbilt campus police to the whistleblower Vanderbilt effectively introduced a chilling effect.



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The IACUC complaint log showed that the IACUC received the complaint on 7/6/08. This is the date that the boyfriend emailed it to several Division of Animal Care employees. On 7/8/09 the IACUC sent him an email response to let him know they received the complaint. Another hard copy letter was sent to him on 7/21/09 with the same information. The email was brought to the attention of the IO by the AV during a regularly scheduled meeting they had. The IO asked that a conference call be held immediately with the IO, the AV, the UMC for legal information and a human resources individual for IIR information. The IO asked that the Chair of the IACUC and the UMC be the subcommittee to investigate the complaint. He felt that because of the human resources issues/protecting the safety of the girlfriend/employee the size of the subcommittee should be limited. This subcommittee started their investigation on 7/8/09 and presented their findings to the full IACUC at their regularly scheduled July 22 meeting. Based on my review of the subcommittee's report and my interview with the UMC it appears that they did a very thorough investigation. The Division of Animal Care (DAC) also set up their own investigation. The IACUC has asked the DAC to present an action plan to make sure the issues don't happen again-it is pending. The actions of the Vanderbilt Police had nothing to do with the complaint but instead were related to the whistleblower stalking his ex-girlfriend.

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Animal
Care

Nicolette
Petervary/NC/APHIS/USDA
05/19/2009 10:29 AM

(b) (6)
[REDACTED]
@peta.org
cc
bcc

Subject letter concerning Vanderbilt University

May 19, 2009

Dear Dr. Chandna:

Thank you for your letter concerning Vanderbilt University.

Animal Care is the division of the U.S. Department of Agriculture (USDA) that is responsible for the enforcement of the Animal Welfare Act (AWA). Among other things, the AWA regulates the use of animals in research, and research facilities that use animals for experimentation and testing are required to be registered with the USDA. The Act also provides minimum standards for the humane care and use of animals at all USDA registered facilities. Specific standards for the care of research animals can be found in the Code of Federal Regulations, Title 9, Subchapter A, and these can be found on our website at http://www.aphis.usda.gov/animal_welfare/index.shtml by clicking on "View Animal Welfare Regulations."

Occupational health and safety standards are not regulated under the Animal Welfare Act. This agency therefore has no authority or jurisdiction over this area of activity. There are, however other Federal, State and County agencies that may be able to assist you with your concerns. We certainly wish the best for the individual who was bitten.

Sincerely,

Nicolette Petervary, VMD
Regional Animal Care Specialist
USDA, APHIS, Animal Care, Eastern Region
920 Main Campus Drive, Suite 200
Raleigh, NC 27606
Tel: 919-855-7101
Fax: 919-855-7123
E-mail: nicolette.petervary@aphis.usda.gov



JUL 21 2008

Animal Care

USDA, APHIS, Animal Care

ANIMAL WELFARE COMPLAINT

Complaint No. 08-171	Date Entered 27 May 2008	Received By T Brasfield
Referred To Brunkhorst/Kirsten		Reply Due 27 Jun 2008

Facility or Person Complaint Filed Against

Name VANDERBILT UNIVERSITY	Customer/License/Registration No. 63-R-0005		
Address AA-6206 MEDICAL CENTER NORTH			
City Nashville	State TN	Zip 37222	Phone No (615) 322-2221

Complainant

(b) (6)	Organization PCRMC	
Washington DC	Zip 20016	(b) (6)

How was complaint received?

Forward response to FOIA: Yes No

Details of Complaint: See letter from PCRMC

Results: As part of a routine inspection I completed at Vanderbilt University this week I reviewed the protocol for the Advanced Trauma Life Support Course offered at Vanderbilt along with two other similar protocols written by the same principal investigator. The principal investigator for the three protocols considered alternatives to procedures that might cause more than momentary or slight pain or distress to any animal used and provided an adequate written narrative describing the methods and sources used as well as an explanation for why he chose not to use certain alternatives found. IACUC meeting minutes reflect that the IACUC reviewed the protocol including the alternative search and explanation and approved the protocols.

Application packet provided? Yes No

INSPECTOR *Susan Brunkhorst, DVM* DATE *6/26/08*
 REVIEWED BY *[Signature]* DATE *7/2/08*



JUL 03 2008

APD
7/2/08
animal
care

USDA, APHIS, Animal Care

ANIMAL WELFARE COMPLAINT

Complaint No. 08-171	Date Entered 27 May 2008	Received By T Brasfield
Referred To Brunkhorst/Kirsten		Reply Due 27 Jun 2008

Facility or Person Complaint Filed Against

Name VANDERBILT UNIVERSITY	Customer/License/Registration No. 63-R-0003		
Address AA-6206 MEDICAL CENTER NORTH			
City Nashville	State TN	Zip 37222	Phone No (615) 322-2231

Complainant

(b) (6)	Organization PCRM		
Address 5100 Wisconsin Ave NW Suite 300			
City Washington	State DC	Zip 20016	(b) (6)

How was complaint received?

Forward response to FOIA: Yes No

Details of Complaint: See letter from PCRM

Results: As part of a routine inspection I completed at Vanderbilt University this week I reviewed the protocol for the Advanced Trauma Life Support Course offered at Vanderbilt along with two other similar protocols written by the same principal investigator. The principal investigator for the three protocols considered alternatives to procedures that might cause more than momentary or slight pain or distress to any animal used and provided an adequate written narrative describing the methods and sources used as well as an explanation for why he chose not to use certain alternatives found. IACUC meeting minutes reflect that the IACUC reviewed the protocol including the alternative search and explanation and approved the protocols.

Application packet provided? Yes No

INSPECTOR

Ausam Bushneit, DVM

DATE

6/26/08

REVIEWED BY

DATE



JUL 03 2008

United States
Department of
Agriculture

MEMO

Marketing and
Regulatory
Programs

From the desk of Susanne Brunkhorst, VMO

Animal and Plant
Health Inspection
Services

June 27, 2008

Re: Complaint 08-171 Vanderbilt University

Animal Care

920 Main Campus Drive
Suite 200
Raleigh, NC 27606

Tel No. 919-855-7100
Fax No. 919-855-7123

I completed a routine inspection at Vanderbilt University the week of June 23, 2008. As part of that inspection I reviewed the protocol for the Advanced Trauma Life Support course (protocol M/06/430). I also reviewed two additional protocols (M/06/431 and M/06/422) by the same Principal Investigator that were similar in scope as they were training protocols using live animals to teach emergency procedures and emergency surgeries.

The Principal Investigator used literature searches to consider alternatives to procedures that might cause more than momentary or slight pain or distress to any animal used and provided adequate written narratives describing the methods and sources used as well as an explanation for why he chose not to use certain alternatives found.

IACUC meeting minutes reflect that the protocols were discussed at full committee review. The IACUC reviewed the protocols including the alternative search and narrative and approved the protocols.

*animal
care*

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08-171

MAY 27 2008

PCRM

P H Y S I C I A N S
C O M M I T T E E
F O R
R E S P O N S I B L E
M E D I C I N E

5100 WISCONSIN AVENUE, N.W., SUITE 400
WASHINGTON, DC 20016
T: (202) 686-2210 F: (202) 686-2216
PCRM@PCRM.ORG WWW.PCRM.ORG

May 21 2008

Via U.S. Mail

Elizabeth Goldentyer, D.V.M.
Regional Director
USDA/APHIS/AC Eastern Region
920 Main Campus Drive, Suite 200
Raleigh, NC 27606

**Re: Use of Live Animals for Advanced Trauma Life Support Courses at the
Vanderbilt University Medical Center**

Dear Dr. Goldentyer:

The Physicians Committee for Responsible Medicine (PCRM) requests that the Animal and Plant Health Inspection Service (APHIS) investigate the unlawful use of live animals in Advanced Trauma Life Support (ATLS) courses at the Vanderbilt University Medical Center.

We believe that this animal use is a violation of the Animal Welfare Act because there are equivalent alternative non-animal technologies available. The TraumaMan System from Simulab has been approved for use in ATLS courses by the program's national oversight body, the American College of Surgeons (ACS). According to the ACS Subcommittee on ATLS and the Executive Committee to the ACS Committee on Trauma, **"an anatomical human body model or manikin may be used in those areas in which the use of live, nonhuman species or human cadavers is cause for significant concern."** This 2001 decision (attached) goes on to describe TraumaMan in detail.

In addition, a 2007-2008 survey of 164 U.S. facilities offering ATLS courses conducted by PCRM found that 148 of those facilities (90 percent) exclusively use non-animal models for instruction and the vast majority of those 148 facilities exclusively use TraumaMan.

Under the Animal Welfare Act, Vanderbilt falls under the statutory definition of a "research facility" and is, therefore, required to comply with the Act. As part of this required compliance, any use of live animals for research, testing, or experimentation must be approved by the school's IACUC.

A fundamental goal of the Act is the elimination of the use of animals in research where possible (see 7 U.S.C. § 2143(d)), and the minimization of animal pain and distress via the consideration of non-animal alternatives (7 U.S.C. § 2143(a)(3)). To this end, Section 2143 of the Act and Title 9, Section 2.31(d)(1)(ii), of the Act's implementing regulations require that a principal investigator (PI) — including course instructors — consider alternatives to procedures that may cause more than momentary or slight pain or distress to any animal used for research purposes.

MAY 27 2008

If the PI determines that no alternatives exist, he or she must provide a written narrative to the institution's IACUC describing the methods and sources used to determine that alternatives were not available. The written narrative should include adequate information for the IACUC to assess that a reasonable and good faith effort was made to determine the availability of alternatives or alternative methods. If a database search or other source identifies a *bona fide* alternative method (one that could be used to accomplish the goals of the animal use proposal), the written narrative must justify why this alternative was not used.

With acknowledgement by ACS that TraumaMan is educationally equivalent to live animals for ATLS training and the overwhelming use of non-animal models at 90 percent of the U.S. facilities that offer the course, **there can be no valid justification for not using TraumaMan in place of live animals.**

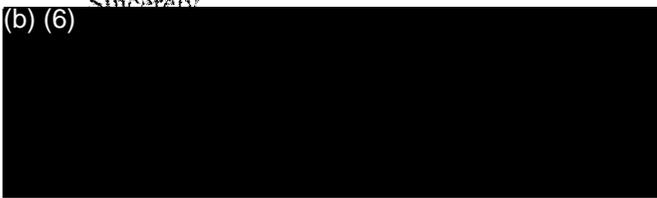
The educational research purposes for which live animals are used at Vanderbilt undoubtedly cause more than momentary or slight pain or distress. Although animals are anesthetized during the procedures themselves, they are subjected to the trauma of continued confinement, shipping, preparation, and experimentation before death in the laboratory.

Given the availability of non-animal technologies and the fact that 90 percent of educational facilities do not use live animals in their ATLS courses, there is no justification for the Vanderbilt IACUC's continued approval of live animal use for this purpose. Instructors who request approval for their use, the IACUC that approves their use, and the medical school that offers this lab as part of its curriculum are in violation of the Act.

Accordingly, the Physicians Committee for Responsible Medicine requests that APHIS investigate this matter to find the Vanderbilt University Medical Center in violation of these animal welfare policies, and kindly requests to be notified of actions taken in response to this complaint.

Sincerely,

(b) (6)



Enclosure



June 5, 2008

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, Unit 3040
Raleigh, NC 27606

(919) 855-7100
(919) 855-7123

(b) (6)

Vanderbilt University Medical Center
S-4322 Medical Center North
1161 21st Avenue South
Nashville, TN 37232

(b) (6)

I am in receipt of your May 1, 2008 letter requesting an exemption to Section §2143 (a)(3)(D) of the AWA and § 2.31 (d)(1)(x) of the AWAR which prohibits the use of an animal in more than one major operative procedure from which it is allowed to recover except when justified for scientific reasons, required to protect the health or well being of the animal, or in special circumstances as determined by the Administrator.

I consulted with Dr. Jodie Kulpa-Eddy and we reviewed your request along with the history and intent of the regulation and similar requests that have come to the department over the years. In general, the intent of the regulation is to minimize pain and distress to individual animals versus minimizing the number of animals used in research. Although the AWA and regulations encourage reduction in the total number of animals used when possible, this particular section was promulgated with the express understanding that additional animals may be required to be used in research in order to minimize the potential pain or distress experienced by individual animals. Additional information would be necessary to justify additional major operative procedures on these animals.

If you would like to resubmit this request please include a detailed description of the procedures that will minimize the potential for pain and/or distress to these animals. Dr. Kulpa-Eddy and I both had specific questions regarding the potential for pain and/or distress from the additional surgeries. Is the total of 20 surgeries described per animal or for the group? Do these include both implants and chamber implantation? Is there a time frame for successive surgeries and an endpoint for deciding when additional surgeries would not be performed? Is there any difference in the parameters between the 2 protocols described? Is there a difference in the plan for the animal that has had 6 prior surgeries and the animal that has had 2?



Thank you and the entire committee for your sensitivity to the importance of this issue. Please call me if you would like to discuss this further.

Sincerely,

A handwritten signature in black ink, which appears to read "Elizabeth Goldentyer". The signature is fluid and cursive, with a large, sweeping flourish at the end.

Elizabeth Goldentyer, DVM
Eastern Regional Director
USDA, APHIS, Animal Care

Cc:
S. Brunkhorst
R. Kirsten
J. Kulpa-Eddy
F. File



(b) (6)

D-3300 Medical Center North
Nashville, TN 37232-2104

(b) (6)

August 13, 2007

Elizabeth J. Goldentyer, DVM, Director, Eastern Region
USDA/APHIS/AC
920 Main Campus Drive, Suite 200
Raleigh, NC 27606-5210

Dear Dr. Goldentyer:

This is to follow up on a preliminary report communicated to Dr. Susanne Brunkhorst on June 01, 2007. During the phone conversation, an animal welfare concern was reported involving cotton rats. In addition, the non-compliance event was conveyed to OLAW.

The Division of Animal Care (DAC) self-reported an animal welfare concern related to cotton rats under their care. The death of three animals appeared to be related to housing and training issues. When the report was made to IACUC/OAWA, a number of steps had already been taken to address the situation. A "for cause" investigation was initiated and the Post Approval Monitoring (PAM) specialist in the Vanderbilt University Office of Animal Welfare Assurance (OAWA) interviewed all personnel involved. The investigation attributed the deaths to a combination of inexperienced personnel and the type of housing used.

The IACUC discussed the incident at a convened meeting held on May 23rd and requested copies of written standard operating procedures and a description of the training provided to DAC personnel (including dates). The DAC responded as follows:

1. The Associate Director of Operations contacted the vendor to review the type of caging used and recommendations for cage changing procedures. After discussion, it was felt that a cage modification was necessary, as well as additional training of DAC personnel on how to safely handle and transfer cotton rats. A Standard Operating Procedure (SOP) on the cage changing process was developed.
2. Specially designed Plexiglas® transfer lids were developed by the VU apparatus shop for use during routine cage changing procedures. These lids minimized the potential for escape/injury during cage change.
3. An SOP, "Cotton Rat Cage Changing", was developed to delineate the steps for cotton rat husbandry including the new cage changing paradigm utilizing the Plexiglas® transfer lids.

4. A training meeting was held on May 14, 2007 with DAC care staff members who are directly assigned to the care of cotton rats. This training included the use of the Plexiglas® transfer lid during the cage changing process and how to handle a cotton rat during transfer. This training session was conducted by the Facility Manager.

5. The use of the newly designed Plexiglas® lids along with the training has minimized the potential for escape/injury during cage change. Since implementing the training and cage modification, no further incidents have occurred.

The VU IACUC herein declares to USDA that this reportable incident was identified and corrected by the IACUC.

Please be assured that VU is committed to the highest standards of compliance related to the humane care and use of animals in research, teaching, and testing. If you have remaining questions/concerns, do not hesitate to contact me (b) (6) PhD, [REDACTED]

Sincerely yours

(b) (6)





Bruckhart
Kirsten
KACC
TN (858) 63-R-0005

United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Marketing &
Regulatory
Programs Business
Services

4700 River Road
Riverdale, MD
20737

Vanderbilt University
AA-6206 Medical Center North
Nashville, TN 37232-2131

CERTIFIED MAIL
RETURN RECEIPT

Dear Sir(s):

Animal and Plant Health Inspection Service (APHIS) enforces regulations to protect the health and care of animals, plants, and agricultural industry. Violations of these regulations jeopardize the animal and plant health systems that are vital to protect American agriculture.

Our investigation shows that you have violated the United States Code of Federal Regulations as described on the enclosed Stipulation. APHIS laws and regulations provide for administrative and criminal penalties to enforce these regulatory requirements.

The Secretary of Agriculture may, after providing notice and opportunity for a hearing, impose civil penalties or other sanctions. You may, however, waive your right to a hearing and settle this matter by paying **\$7,219 by August 31, 2007**, and signing the enclosed Stipulation.

Please pay the \$7,219 penalty by certified check or money order made payable to the Treasurer of the United States. Write the Case Number (Case No. TN06143-AC) on your check or money order and mail it with the signed Stipulation to:

USDA, APHIS, (General) (Case No. TN06143-AC)
P. O. Box 979043
St. Louis, MO 63197-9000

If we do not receive your signed stipulation agreement and payment or notice that you wish to exercise your right to a hearing by August 31, 2007, this matter will be forwarded to the Department's Office of the General Counsel for litigation. The penalty offered in this Stipulation is not relevant to the sanctions APHIS may seek, or that will be assessed after issuance of a formal complaint. You may contact our office at telephone number (301) 734-8684 if you have any questions.

Sincerely,

Allison Khroustalev
Assistant Director, Enforcement
Investigative and Enforcement Services

Enclosure

cc: J. Kinsella, IES-ER, Raleigh, NC

E. Goldentyer, AC-ER, Raleigh, NC

APHIS:IES(b)(6)(b)(7)(C) 78:7-27-07:i:\tm06143 sag ltr.doc



Safeguarding American Agriculture
APHIS is an agency of USDA's Marketing and Regulatory Program

An Equal Opportunity Provider and Employer

Investigative and Enforcement Services

Settlement Agreement

USDA, APHIS, IES
4700 River Road, Unit 85
Riverdale, MD 20737
Phone: (301) 734-8684
Fax: (301) 734-4328

RESPONDENT:

Vanderbilt University
AA-6206 Medical Center North
Nashville, TN 37232-2131

CASE NUMBER TN06143-AC
DUE ON OR BEFORE August 31, 2007

(b)(6)(b)(7)(C)

DATE	CITATION	DESCRIPTION

PENALTY \$7,219.

TERMS

Titles 7, 15, 19, and 21 of the United States Code authorize the Secretary of Agriculture, after providing notice and opportunity for a hearing, to impose civil penalties and other sanctions to resolve violations.

Prior to the issuance of a formal complaint seeking sanctions under the Act, The Department may enter into a stipulation to resolve the above-described violations. Your payment constitutes a waiver of your right to a hearing, a finding that the violations of law have occurred, and settlement of such violations.

If you do not pay the specified penalty within the designated time or wish to exercise your right to a hearing, this matter will be forwarded to the Office of the General Counsel for litigation. The penalty offered in this stipulation is not relevant to the sanctions the Department may seek, or that will be assessed, upon issuance of a formal complaint.

Signature of Respondent: _____ **Date:** _____

PAYMENT RECORD - FOR IES USE ONLY

Payment Type	Date	Amount	Signature of IES Representative

DATE

CITATION
9 CFR

DESCRIPTION

30 JUN 06

2.31(c)(3)

Institutional Animal Care and Use Committee (IACUC).
Failure to submit semi-annual facility inspection and program review to the institution official in a timely fashion. Review and inspection was conducted and completed January 9-13, 2006, and was not submitted until March 2006. Failure to submit semi-annual facility inspection and program review to the institution official with a majority of the IACUC members signature on the report. Signature page left off of the report.

2.31(d)(1)(i)

Institutional Animal Care and Use Committee (IACUC).
Records for primate R5715F shows that no water was given on 6/25/06 which would have caused the animal to be in discomfort, distress, or pain. Also failed to record weights as required.

2.31(d)(1)(ii)

Institutional Animal Care and Use Committee (IACUC).
Approved protocol C/0/106 with an alternative search that was not complete. The protocol was approved without the alternative key words for painful procedures. Approved protocol M/05/319 with an alternative search that was not complete. The protocol was approved without the alternative keywords for the species of animal to be used and painful procedures. Repeat non-compliance from December 8, 2005.

2.31(e)(2)

Institutional Animal Care and Use Committee (IACUC).
Approved protocol C/05/106 without justification for the number of animals that were going to be used. IACUC approved protocol M/03/067 with a justification for the number of animals that were going to be used.

2.31(e)(3)

Institutional Animal Care and Use Committee (IACUC).
IACUC failed to discover upon monitoring or review that the researcher was not giving fluid rewards after each correct trial as required in protocol C/05/106. Repeat failure to discover upon monitoring or review that the amount of fluids being consumed during ad lib periods were not being recorded as required in protocol C/05/106. The use of ultrasound was not approved for protocol M/05/319; ultrasound was used on all rabbits involved in this program. Acepromazine is being administered as part of the procedures involving protocol M/05/319; acepromazine has not been approved for use in this protocol. IACUC failed to discover upon monitoring or review that protocol M/02/187 did not include a complete use description of the animals. IACUC failed to discover upon monitoring or review that non-approved enucleations were performed but not described in protocol M/02.303.

<u>DATE</u>	<u>CITATION</u> 9 CFR	<u>DESCRIPTION</u>
30 JUN 06	2.31(d)(1)(viii)	Institutional Animal Care and Use Committee (IACUC). Untrained and unapproved personnel performed surgical procedures, post surgical care, and experimental procedures but were not listed on the approved protocol. IACUC approved protocol M/03/067 with all personnel listed as having no experience with handling ferrets. IACUC approved protocol M/05/345 with two personnel listed as having no experience with species or techniques.
	2.33(b)(5)	Attending veterinarian and adequate veterinary care. Adequate post-procedural care was not given in accordance with the established protocol procedures. Rabbits involved in protocol M/05/319 were not administered Buprenex when pain was observed. Adequate care was not given in accordance with the established protocol procedures. Rabbits were not administered bupivacaine as directed in protocol M/05/319. Adequate care was not given in accordance with the established protocol procedures. Bush baby #6-02-1 was not administered Ceftriaxone as directed in protocol M/02/303. Failed to provide adequate post-procedural care for a ferret that died after a surgical procedure. Adequate care was not given in accordance with the established protocol by failing to keep records for the use of a neuromuscular blocker, anesthetic and ventilation regarding cat research pertaining to protocol M/04/345.
	2.31(d)(1)(ix)	Institutional Animal Care and Use Committee (IACUC). IACUC approved protocol M/02/187 without an adequate description of anesthesia, pre-operative and intra-operative care because the surgery was described as euthanasia instead of a non-survival surgery. IACUC approved protocol M/02/303 for survival surgery; on February 13, 2006, a bush baby was subject to enucleation surgery for which there is no provision in the protocol.
	2.31(e)(4)	Institutional Animal Care and Use Committee (IACUC). IACUC; a new anesthesia regimen was used on ferret research involving protocol M/03/067 before the IACUC approved the amendment requesting approval for the use of a new anesthesia.
	2.32(a)&(b)	Personnel qualifications. Failure to ensure that all their personnel were trained to perform their duties and responsibilities.
	2.33(b)(2)	Attending veterinarian and adequate veterinary care. Failed to maintain an acceptable veterinary practice regarding the use and storage of expired drugs.

<u>DATE</u>	<u>CITATION</u> 9 CFR	<u>DESCRIPTION</u>
30 JUN 06	2.36(b)(3)	Annual Report. Failed to maintain a complete annual report by not including a summary of the exceptions involving the restriction of water of non-human primates in IACUC approved protocols.
	3.1(c)(2)	Housing facilities, general. Failed to maintain the surface of a study table and surrounding area in room A1 cleaned and sanitized. Failed to maintain the surface of a transport cart in room C1 cleaned and sanitized.
	3.28(e)(1)(iii)	Primary enclosures, guinea pigs. Failed to provide adequate space for guinea pig housing. Guinea pig enclosures were too small for the number of animals being housed within.
	3.53(a)(2)	Primary enclosures, rabbits. Failed to provide adequate clean, dry housing for rabbits. Rabbit enclosures were found to be dirty with fecal material adhering to the floor of the cage.
	3.81	Environment enhancement to promote psychological well-being. Failed to provide enrichment to two primates by not providing daily fruit as described in their enrichment program.
	3.82(d)	Feeding. Failed to keep food receptacles clean and sanitized.
	3.84(a)	Cleaning, sanitization, housekeeping, and pest control. Failed to maintain clean and sanitized living environment by allowing fecal material to build up under the macaques enclosure. Failed to maintain clean and sanitized living environment by allowing fecal material to build up under the primates enclosure.
	3.131(a)	Sanitation. Failed to maintain a clean and sanitized living environment by allowing fecal material to build up on the floor and cages of the ferret enclosures.
4 DEC 06	2.31(d)(1)(i)	Institutional Animal Care and Use Committee (IACUC). IACUC failed to avoid the discomfort, distress, and pain of an animal by performing a durascrape procedure on a non-human primate without the use of anesthetics or analgesics.
04 JAN 07	2.32(a) 2.38(f)(1)	Personnel Qualifications. Failed to train their personnel in order to perform their duties: specifically in regard to the death of a rabbit in the cage washer. Failed to handle animals in their possession that did not cause stress, trauma, or death. Rabbit killed in cage washer.

<u>DATE</u>	<u>CITATION</u> 9 CFR	<u>DESCRIPTION</u>
05 JUN 07	2.31(d)(1)(viii)	Institutional Animal Care and Use Committee (IACUC). unapproved personnel performed surgical procedures but was not listed on the approved protocol M/06/330.
	2.31(d)(2)	Institutional Animal Care and Use Committee (IACUC). Failed to provide each member of the committee with the list of proposed activities to be reviewed.
	2.31(d)(5)	Institutional Animal Care and Use Committee (IACUC). Shall conduct continuing reviews of activities; dog 413 on protocol M/06/399 did not receive Simplicef as described in the approved protocol and rabbit 984 on protocol m/06/330 was not administered Cefazolin as described in the approved protocol.
	2.31(e)(3)	Institutional Animal Care and Use Committee (IACUC). Failed to discover upon monitoring or review that Protocol M/06/394 did not include a complete and accurate description of animal procedures, use of animals, and does not include a listing of possible adverse reactions.
	2.32(a) 2.38(f)(1)	Personnel qualifications. Failure to ensure that all their personnel were trained to perform their duties and responsibilities. Failed to handle animals as carefully as possible; three cotton rats killed/died during routine cage changes.
	2.33(b)(2)	Attending veterinarian and adequate veterinary care. Failed to maintain an acceptable veterinary practice regarding the use and storage of expired drugs; expired triple antibiotic ointment being used to treat wounds on a mole rat.
	2.33(b)(3)	Attending veterinarian and adequate veterinary care. Failed to apply acceptable veterinary care practices regarding daily observations and or communication with an attending veterinarian; naked mole rat with injuries from a fight not conveyed to attending veterinarian.
	2.35(a)	Recordkeeping requirements. Failure to maintain complete records. IACUC meeting minutes must include records of all activities and deliberations.
05 JUN 07	2.35(d)(4)	Recordkeeping requirements. Failure to notify in writing, principal investigators and the research facility of decisions to approve or withhold approval of activities.

DATE

CITATION
9 CFR

DESCRIPTION

05 JUN 07

3.11(c)

Cleaning, sanitization, housekeeping, and pest control. Failed to maintain premises clean and in good repair; rack with mop and buckets dirty and discolored. Floor in the area around drain has cracks in concrete and standing water.

3.53(a)(5)

Primary enclosures. Failed to provide suitable nest box with clean nesting materials in each primary enclosure: Does 118, 119, 117, and 120 enclosures did not contain suitable nest. Flooring of one cage had openings that could potentially cause injury to the animal housed within.

Enforcement Action Option Worksheet

Date of Enforcement Action Request <u>6/18/07</u>	
Name of violator <u>Vanderbilt University</u>	Customer # <u>858</u> License/Registration # <u>63-R-0005</u>
Action Requested (Check all that apply)	
<input checked="" type="checkbox"/> There is a current Open Investigation. Case No. <u>TN06143</u> Attached information is submitted as additional information for an open case	
<input type="checkbox"/> No Action	Explanation: <input type="checkbox"/> Violation(s) are not severe enough to necessitate further enforcement action at this time. <input type="checkbox"/> There is evidence that the facility is making credible progress towards full compliance. <input type="checkbox"/> Other
<input type="checkbox"/> LOI on 2 nd Attempted Inspection <input type="checkbox"/> LOI on repeat NCI's <input type="checkbox"/> 7060 <input type="checkbox"/> Investigation to acquire information <input type="checkbox"/> Investigation for a stipulation <input type="checkbox"/> Investigation for administrative prosecution by OGC <input type="checkbox"/> New License Application Denial <input type="checkbox"/> Renewal Application Denial <input type="checkbox"/> License termination	
Carrier Inspection Report with NCIs	
Is there injury, escape, or death involved? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Supporting Information Attached	
Inspection Report Date: <u>06/05/07</u> Customer # <u>858</u> Report # <u>264486</u> Site # <u>4336</u>	Inspection Report Date: Customer # Report # Site #
<input type="checkbox"/> There is a complaint. Complaint Number: _____ <input checked="" type="checkbox"/> This is a self reported incident.	
Photos Included (Required for all photographable NCIs) <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Explanation: <u>Copies of records available</u>	
Airway bill Included <input type="checkbox"/> Yes <input type="checkbox"/> No Explanation:	
Inspector Name: <u>Susanne Brunkhorst</u> Date <u>6/18/07</u> Inspector Comments (include why action is requested): <u>Additional info for open case</u>	
Action Requested or SACS Comments SACS Name: <u>P.R. Kirsten</u> Date <u>6/18/07</u> <u>Please send on for open investigation.</u>	
Action Taken or Office Comments Reviewer Initials: Date <u>Send to IFS</u> <u>ACC</u> <u>6-22-07</u>	



April 3, 2007

United States
Department of
Agriculture

Marketing and
Regulatory
Programs

Animal and Plant
Health Inspection
Services

Animal Care

920 Main Campus Drive
Suite 200
Raleigh, NC 27606

Tel No. 919-855-7100
Fax No. 919-855-7123

(b) (6)

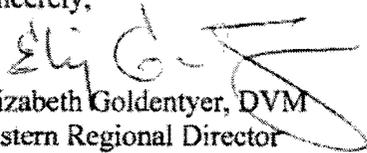
Vanderbilt University Medical Center
D-3300 Medical Center North
Nashville, TN 37232-2104

Dear (b) (6)

Your request for an extension of time to fully implement the corrections to Section 2.32 Personnel Qualifications is approved. The new date for full implementation is March 30, 2008.

We appreciate your attention to these matters and the progress you have made in personnel training and qualifications. If you have any questions or concerns, please do not hesitate to contact your inspector, Dr. Susanne Brunkhorst at (703) 812-6935 or our office at (919) 855-7100.

Sincerely,


Elizabeth Goldentyer, DVM
Eastern Regional Director
Animal Care

Cc:
R. Kirsten
S. Brunkhorst
63-R-0005

Animal Care is a part of the Department of
Agriculture's Animal and Plant Health Inspection Service

An Equal Opportunity Provider and Employer

*animal
care*

 Vanderbilt University Medical Center

1D-3300 Medical Center North
Nashville, TN 37232-2104

(b) (6)

APR 6 2007

(b) (6)

March 26, 2007

Elizabeth J. Goldentyer, DVM, Director, Eastern Region
USDA/APHIS/AC
920 Main Campus Drive, Suite 200
Raleigh, NC 27606-5210

Dear Dr. Goldentyer,

On June 30, 2006, Dr. Suzanne Brunkhorst conducted an inspection of Vanderbilt University's (VU) animal care and use program (Certificate #63-R-0005). Among the items of non-compliance listed on the report was one under the heading "Section 2.32 Personnel Qualifications." While significant progress has been made in VU's training program for personnel, additional improvements are planned and these will take time to implement fully. This letter requests an extension of the March 30, 2007 "correct by" date listed on the report.

In September 2006, the VU training program for personnel using animals was expanded to include other on-line training modules offered by the Veterans Administration (VA) Office of Research and Administration. In addition to the module, "Working with the IACUC (Non-VA Version)," persons listed on protocols are now required to complete the relevant on-line courses for the species/procedures used/performed. Principal investigators must complete the relevant modules for all species/procedures used/performed in their laboratory. All personnel listed on active protocols completed the new training requirements as part of an October 2006 mandatory resubmission of protocols involving USDA regulated species. In addition, a post-approval compliance monitoring program was implemented last year. The program, which involves visits to laboratories to observe procedures, has greatly enhanced our ability to ensure that training and qualifications of personnel are appropriate to the procedures performed.

With the arrival of (b) (6), who joined VU on January 1, 2007 as (b) (6), VU is poised to continue making significant progress in the area of personnel training and qualifications. The OAWA, together with Division of Animal Care (DAC) veterinarians, will develop several "hands on" training workshops which will be made available to research faculty and staff in the coming months. This effort will coincide with ongoing contract negotiations between the DAC and Charles River Laboratories, Inc. to develop written standard operating procedures and a formal training program for DAC personnel.

We anticipate these training efforts will be substantially aligned in the next six months and fully implemented in a year. Hence, please consider our request for an extension beyond the current deadline of March 30, 2007.

Thank you for your consideration of this request. The faculty and staff (DAC, IACUC/OAWA, and research) are working hard to implement improvements in our animal care and use program, and will continue to work with Dr. Brunkhorst and USDA-Animal Care to address these issues. Should you have questions or concerns about this memorandum or Vanderbilt University's commitment to addressing the issues identified by USDA-Animal Care, please contact me or (b) (6)

Sincerely,

(b) (6)

(b) (6)

Vanderbilt University

cc.

(b) (6)



July 3, 2007

United States
Department of
Agriculture

Marketing and
Regulatory
Programs

Animal and Plant
Health Inspection
Services

Animal Care

920 Main Campus Drive
Suite 200
Raleigh, NC 27606

Tel No. 919-855-7100
Fax No. 919-855-7123

Michael A. Budkie
SAEN
1081-B St. Rt. 28 PMB 280
Milford, OH 45150

Dear Mr. Budkie:

Thank you for your letter dated 07-Jul-07 concerning Vanderbilt University located in Nashville, TN. Your concern has been given number 07-212. Please refer to this number when inquiring about this concern.

Your concerns have been documented, and we are aware of the inspection report findings. Please be assured that we have evaluated the situation and will be taking enforcement action if necessary.

Thank you for your concern for the welfare of animals.

Sincerely,

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

Animal Care

Animal Care is a part of the Department of Agriculture's Animal and Plant Health Inspection Service.

An Equal Opportunity Provider and Employer

Stop Animal Exploitation NOW!**1081-B St. Rt. 28 PMB 280****Milford, Ohio 45150****saen@saenonline.org 513-575-5517**

Dr. Elizabeth Goldentyer
USDA/APHIS/AC
920 Main Campus Drive
Suite 2000
Raleigh, NC 27606

7/3/07

Dr. Goldentyer,

I am contacting you regarding a matter of the utmost urgency and importance. I am in possession of a series of three USDA/APHIS/AC inspection reports for Vanderbilt University for the period 5/3/05 – 6/26/06. In these reports the number of violations listed has increased steadily from 13 in May of 2005 to 20 in June of 2006. These infractions are very serious in nature, and are of a recurring regularly. The inspection report for December of 2005 lists 4 repeat non-compliances and the June of 2006 inspection turned up 7 repeat infractions.

It is quite apparent that the officials supervising the care of animals at Vanderbilt University have no regard whatsoever for either the well-being of animals within their facility, or for the regulatory authority of the USDA/APHIS/AC.

The violations at this facility are serious, they jeopardize both the welfare of the thousands of animals experimented on annually within this facility and the safety of humans whose health is potentially influenced by improperly performed medical research.

The multiple violations by Vanderbilt's Institutional Animal Care & Use Committee, the use of unqualified personnel, violations of standards for veterinary care, reporting, housing/enclosures, environmental enhancement for primates and even in such basic areas as feeding and sanitation make it obvious that the supervisory staff of this lab have nothing but contempt for federal laws.

It is clear that nothing short of serious action on the part of your agency will bring this facility into compliance with federal regulations for animal research and care. Therefore, I hereby request that you immediately initiate proceedings against this criminal laboratory and that the largest fine allowable under current law is levied as soon as is legally possible.

I would also request that you provide me with a written determination of this process when it is completed.

Sincerely,

Michael A. Budkie, A.H.T.

Michael A. Budkie, A.H.T.,
Executive Director, SAEN



April 3, 2007

United States
Department of
Agriculture

Marketing and
Regulatory
Programs

Animal and Plant
Health Inspection
Services

Animal Care

920 Main Campus Drive
Suite 200
Raleigh, NC 27606

Tel No. 919-855-7100
Fax No. 919-855-7123

(b) (6)

Vanderbilt University Medical Center
D-3300 Medical Center North
Nashville, TN 37232-2104

Dear (b) (6):

Thank you for your letter of August 13, 2007 concerning an animal welfare concern at Vanderbilt University. This will be helpful to USDA, APHIS, Animal Care. Please convey our thanks to the Animal Care staff.

If you have any questions or concerns, please do not hesitate to contact your inspector, Dr. Susanne Brunkhorst at (703) 812-6935 or our office at (919) 855-7100.

Sincerely,

Elizabeth Goldentyer, DVM
Eastern Regional Director
Animal Care

Cc:
R. Kirsten
S. Brunkhorst
63-R-0005

*animal
care*

Animal Care is a part of the Department of
Agriculture's Animal and Plant Health Inspection Service

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