



May 17, 2011

United States  
Department of  
Agriculture

Animal and  
Plant Health  
Inspection  
Service

Michael Budkie  
[saen@saenonline.org](mailto:saen@saenonline.org),  
Sent Via Email

Legislative and  
Public Affairs

Dear Mr. Budkie:

Freedom of  
Information

This is in response to your January 13, 2011, Freedom of Information Act (FOIA) request for copies of all documents generated by the current investigation of the University of Wisconsin, Madison research facilities relevant to violations of the Animal Welfare Act. Your request was received in this office on January 13, 2011, and assigned FOIA 11-189. We apologize for the delay of this response.

4700 River Road  
Unit 50  
Riverdale, MD  
20737-1232

Agency employees conducted a thorough search of their files and located a voluminous amount of documents of records that are responsive to your request. With this letter, we are providing 22 pages of releasable records responsive to your request. However, portions of the information is being withheld pursuant to FOIA Exemption 6, 5 U.S.C. § 552 (b)(6). This exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. The same information has been withheld pursuant to FOIA Exemption 7(C), 5 U.S.C. § 552 (b)(7)(C). This exemption protects from disclosure records or information collected for law enforcement purposes when its release could reasonably be expected to constitute an unwarranted invasion of personal privacy. Specifically, we have withheld the identity of third party's individuals.

Please be advised, the documents you have requested are involved in an ongoing investigation, therefore, we are withholding the remaining records pursuant to FOIA Exemption 7(A), 5 U.S.C. § 552(b)(7)(A). This exemption protects from disclosure records compiled for law enforcement purposes, the release of which could reasonably be expected to interfere with enforcement activities. Moreover, we are unable to determine when the proceeding will be completed. You are welcome to submit a new request for this information at a later date.

You may appeal our partial denial of information. If you choose to appeal, your appeal must be in writing and must be received within 45 days of the date of this letter at the following address:

Administrator  
Animal and Plant Health Inspection Service  
Ag Box 340  
Washington, DC 20250-3401



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

An Equal Opportunity Provider and Employer

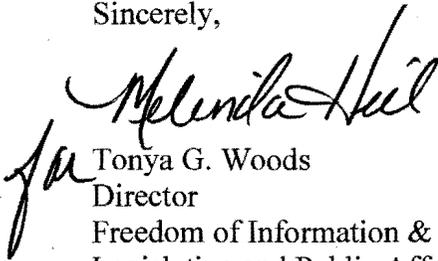
Mr. Michael Budkie  
FOIA 11-189

2

If you choose to appeal, please refer to FOIA 11-189 in your appeal letter and add the words "FOIA Appeal" to the front of the envelope. To assist the Administrator in reviewing your appeal, provide specific reasons why you believe modification of the determination is warranted.

Because the cost to process your request is less than \$25.00, the fee has been waived. If you have questions, please contact Ms. KeWanda McCain of my staff at (301) 734-4893.

Sincerely,

A handwritten signature in cursive script, appearing to read "Tonya G. Woods". To the left of the signature is a small, stylized handwritten mark that looks like "ja".

Tonya G. Woods  
Director  
Freedom of Information & Privacy Act  
Legislative and Public Affairs

Enclosures

111 . 189

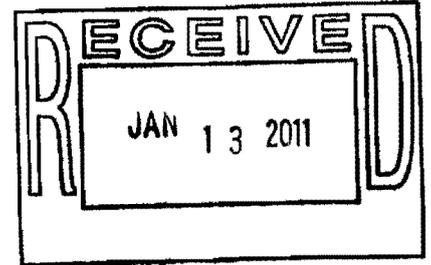
*Ke Wanda  
DES  
Individual*



"Michael Budkie"  
<saen@saenonline.org>  
01/13/2011 02:57 PM

To <foia.officer@aphis.usda.gov>  
cc  
bcc  
Subject FOIA Request

**SAEN**  
**1081-B St. Rt. 28 PMB 280**  
**Milford, Ohio 45150**  
**513-575-5517**  
**www.saenonline.org**



FEB 11 2011

1/13/11

Dear FOIA Coordinator,

This request for records is made under the federal Freedom of Information Act, 5 U.S.C. sec. 552.

As a coordinator for SAEN, in Milford, Ohio, I am making this request. SAEN is a non-profit organization based in Milford, Ohio, dedicated to educating the public about issues concerning animal rights. SAEN may be hereafter be referred to as "the requester".

This request is directed at obtaining copies of: all documents generated by the current investigation of the University of Wisconsin, Madison research facilities relevant to violations of the Animal Welfare Act. These documents are to include reports, memos, correspondence, veterinary records, photos, videos, etc. relevant to this investigation.

If any of the records or documents described above are considered to be exempt from release, please segregate and provide access to non-exempt portions, and justify deletions by reference to specific exemptions in the Freedom of Information Act.

The requester is prepared to pay all reasonable search and duplication fees up to an initial amount of one hundred dollars (100.00). However, the Freedom of Information Act provides that: "Documents shall be furnished without cost or at a reduced charge where the agency determines that waiver or reduction of the fee is

in the public interest because furnishing the information can be considered as primarily benefiting the general public," (See 5 U.S.C., sec. 552 (a) (4) (9A).)

The requester believes that this request satisfies the criteria for fee waiver or reduction: 1. SAEN is a non-profit, public interest group whose tax-exempt number is 31-1481336; 2. The use of live animals in experimentation has historically been a matter of wide public interest; 3. The disclosure of the requested records would not be to the primary benefit of the requester, but would be to the primary benefit of the general public. SAEN has demonstrated its ability to disseminate to the general public the information it acquires. This is achieved by reliable media contacts, and a nationally distributed activist base.

Therefore, the requester asks that any search or duplication fees in this case be waived or reduced. If the waiver or reduction is denied, and fees exceed one hundred dollars (100.00), please notify the requester by telephone before the request is processed so the requester may decide whether to pay the higher fee or to appeal the denial of the request for waiver reduction.

I may be reached during business hours at 513-575-5517. If you have any questions regarding any aspect of this request, please contact me by telephone rather than by mail in order to expedite timely disclosure.

Thank you for your assistance. I will look forward to receiving your reply within ten (10) business days as is required by law.

Sincerely,

Sincerely,

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

Every research facility, exhibitor, carrier, and intermediate handler must be licensed under Section 3 of the Animal Welfare Act, information for such registration. Public reporting burden for this collection of information is estimated to average 25 hours per existing data source, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, D.C. 20250, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

JEC 3 11 2008

FORM APPROVED  
OMB NO. 0579-0036

<p><b>U.S DEPARTMENT OF AGRICULTURE</b> <b>ANIMAL AND PLANT HEALTH INSPECTION SERVICE</b></p> <p><b>APPLICATION FOR REGISTRATION</b> (TYPE OR PRINT)</p> <p><b>REGISTRATION UPDATE</b></p>	<p style="text-align: center;"><b>DO NOT USE THIS SPACE - OFFICIAL USE ONLY</b></p> <p>SEND THE COMPLETED FORM TO: 920 Main Campus Drive Suite 200, Unit 3040 Raleigh, NC 27606 Telephone: (919) 855-7101</p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%; text-align: center;">CERTIFICATE / CUSTOMER NO.</td> <td style="width:50%; text-align: center;">REGISTRATION UPDATE</td> </tr> <tr> <td style="text-align: center;">CERTIFICATE: 35-R-0001 CUSTOMER: 616</td> <td style="text-align: center;">07-JAN-2009</td> </tr> </table>	CERTIFICATE / CUSTOMER NO.	REGISTRATION UPDATE	CERTIFICATE: 35-R-0001 CUSTOMER: 616	07-JAN-2009
CERTIFICATE / CUSTOMER NO.	REGISTRATION UPDATE				
CERTIFICATE: 35-R-0001 CUSTOMER: 616	07-JAN-2009				

<p><b>1. NAME(S) OF REGISTRANT(S) AND MAILING ADDRESS</b></p> <p>University Of Wisconsin-Madison</p> <p>Director Research Animal Resources Center 1710 University Avenue 396 Enzyme Inst Madison, WI 53726 4087</p> <p>Telephone: (608) 262-1238</p>	<p><b>2. ALL BUSINESS LOCATIONS HOUSING ANIMALS; INCLUDE DIRECTIONS TO EACH LOCATION (P.O. Box not acceptable)</b></p> <p>500 Lincoln Dr. 161 Bascom Madison, WI 53706 County: Dane</p> <p>Telephone:</p>
<p><b>3. (A) PREVIOUS USDA REGISTRATION NUMBER (if any)</b></p> <p>35- R-0001</p>	<p><b>4. (B) ACTIVE USDA CERTIFICATE NUMBER(S) IN WHICH YOU HAVE AN INTEREST:</b></p> <p>35-R-0001</p>
<p><b>5. ARE YOU USING FEDERAL FUNDS TO CARRY OUT RESEARCH, TESTS, OR EXPERIMENTS (if yes, go to item 6)</b></p> <p><input checked="" type="checkbox"/> Yes      <input type="checkbox"/> No</p>	<p><b>6. TYPE OF REGISTRATION:</b></p> <p><input type="checkbox"/> Class E - Exhibitor      <input type="checkbox"/> Class H - Intermediate Handler <input checked="" type="checkbox"/> Class R - Research Facility      <input type="checkbox"/> Class T - Carrier</p>
<p><b>7. FEDERAL FUND TYPE(S):</b></p> <p><input type="checkbox"/> Award    <input type="checkbox"/> Contract    <input checked="" type="checkbox"/> Grant    <input type="checkbox"/> Loan</p>	<p><b>8. TYPE OF ORGANIZATION:</b></p> <p><input type="checkbox"/> Individual    <input type="checkbox"/> Corporation    <input type="checkbox"/> Partnership <input checked="" type="checkbox"/> Other (Specify) <u>University</u></p>

**9. IF INDIVIDUAL, IDENTIFY EACH OWNER, IF PARTNERSHIP IDENTIFY EACH PARTNER OR OFFICER, IF CORPORATION, IDENTIFY PRINCIPAL OFFICERS FOR RESEARCH FACILITIES INCLUDE THE INSTITUTIONAL OFFICIAL (Use separate sheet if needed)**

A. NAME	B. TITLE	C. ADDRESS (Full Address, including Zip Code)
(b)(6),(b)(7)c	Chancellor	161 Bascom Hall, 500 Lincoln Dr. Madison, WI 53706
	Vice Chancellor for Research	333 Bascom Hall, 500 Lincoln Dr. Madison, WI 53706
	Dean, Graduate School	
	Assoc. Dean for Research Policy	333 Bascom Hall, 500 Lincoln Dr. Madison, WI 53706

**CERTIFICATION**

I hereby register as a Research Facility, Exhibitor, Carrier, or Intermediate Handler under the Animal Welfare Act 7 U.S.C. 2131 et seq. I certify that the information provided herein is true and correct to the best of my knowledge. I hereby acknowledge receipt of and agree to comply with all the regulations and standards in 9 CFR, Subpart A, Parts 1, 2 and 3. I certify that all listed persons are 18 years of age or older.

(b)(6),(b)(7)c	12. SOCIAL SECURITY OR TAX IDENTIFICATION NUMBER	13. DATE <u>12-22-08</u>
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**United States  
Department of  
Agriculture**

**Marketing and  
Regulatory  
Programs**

**Animal and  
Plant Health  
Inspection  
Service**

**Animal Care**

**EXPIRATION DATE: JANUARY 7, 2012**

This is to certify that

**UNIVERSITY OF WISCONSIN-MADISON**

is a registered  
under the

**CLASS R RESEARCH FACILITY**

## **Animal Welfare Act**

**(7 U.S.C. 2131 et seq.)**

Certificate No.           **35-R-0001**

Customer No.           **616**

A handwritten signature in black ink, appearing to read "Charles A. Simpson". The signature is written in a cursive style and is positioned above a horizontal line.

**Deputy Administrator**

SH

According to the Paperwork Reduction Act of 1996, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED  
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2160.

Interagency Report Control  
No. 0180-DQA-AN

Fiscal Year: 2009

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

REGISTRATION NUMBER: 35-R-0001

Customer Number: 616

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include ZIP Code)

University Of Wisconsin-Madison  
Director Research Animal Resources Center  
1710 University Avenue 396 Enzyme Inst  
Madison, WI 53726

Telephone: (608) 262 1238

ANNUAL REPORT OF RESEARCH FACILITY  
(TYPE OR PRINT)

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites) See Attached Listing

(see attached)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A.)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedure, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	14	59	171		230
5. Cats	6	34	9		43
6. Guinea Pigs		1			1
7. Hamsters	109	194	376		570
8. Rabbits	2	21	48		69
9. Non-human Primates	859	779	768		1,547
10. Sheep	6	7	119		126
11. Pigs		63	131		194
12. Other Farm Animals					
13. Other Animals					
Bear		14			14
Chinchilla		15	59		74
Deer		1			1

ASSURANCE STATEMENTS

(continued)

- 1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2.) Each principal investigator has considered alternatives to painful procedures.
- 3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (L.R.O.))

(b)(6),(b)(7)c

DATE SIGNED

11-23-09

26 12-9-09

NOV 30 2009

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED  
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control  
No. 0180-00A-AN

Fiscal Year: 2009

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE  
**CONTINUATION SHEET FOR ANNUAL  
REPORT OF RESEARCH FACILITY**  
(TYPE OR PRINT)

REGISTRATION NUMBER: 35-R-0001

Customer Number: 816

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include ZIP Code)

University Of Wisconsin-Madison  
Director Research Animal Resources Center  
1710 University Avenue 398 Enzyme Inst  
Madison, WI 53726

Telephone: (608) 262 1238

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
13-lined ground squirrel		25	105		130
cow		133	159		292
ferret		15	124		139
gerbil	3	123	40		163
horse			42		42
chipmunk		355			355
squirrel		198	148		346
raccoon		5			5
vole		4			4
wild mice	500	282	215		497

ASSURANCE STATEMENTS

- 1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2.) Each principal investigator has considered alternatives to painful procedures.
- 3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (L.R.O.))  
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR L.O.	NAME AND TITLE OF C.E.O. OR L.O. (Type or Print)	DATE SIGNED
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APHIS FORM 7023A  
AUG 2009

NOV 30 2009

APHIS Form 7023 Site Addendum for FY: 2009

ARS Arlington Sheep  
Arlington, WI

Animal Health & Biomedical Sciences  
Madison, WI

ARS Arlington Soil and Swine  
Arlington, WI

ARS Arlington Vet Sci (Bookhout)  
Arlington, WI

Dairy Cattle Center  
Madison, WI

SVM CIF (Charmany Farm)  
Madison, WI

Livestock Laboratory  
Madison, WI

Influenza Research Institute  
Madison, WI

Nutritional Sciences  
Madison, WI

Veterinary Medicine Building  
Madison, WI

US-Forage Research Center  
Prairie du Sac, WI

Harlow Center for Biological Psychology  
Madison, Wisconsin

Biotron Laboratory  
Madison, WI

Primate Center  
Madison, WI

Primate Center Annex  
Madison, WI

Waisman Center  
Madison, WI

Wisconsin Institutes Medical Research  
Madison, WI

Bardeen Medical Laboratories  
Madison, WI

Clinical Science Center  
Madison, WI

McArdle Cancer Research  
Madison, WI

Medical Sciences Center  
Madison, WI

Meriter Hospital  
Madison, WI

Microbial Sciences  
Madison, WI

Service Memorial Institute  
Madison, WI

UW Psychiatric Institute and Clinics  
Madison, WI

**IACUC APPROVED EXCEPTIONS TO THE STANDARDS AND  
REGULATIONS OF THE USDA ANIMAL WELFARE ACT  
INVOLVING CAMPUS ANIMALS**

**Reporting Period: 10/01/08 – 09/30/09**

**Justification for and Extent of Cleaning/Sanitizing Exemptions:**

- There are IACUC approved protocols for 46 rhesus macaques and 20 cynomolgus macaques – exempted from cage cleaning for 72 hours following MPTP administration. During this reporting period, no animals were used on these protocols.

**Justification for Cage Size Exemption:**

- There is an IACUC approved protocol for up to 300 rhesus macaques – exempted from cage size requirement when a breeding pair is housed in a single 6.0 sq. ft. cage for up to 14 days. During this reporting period, 286 animals were paired for breeding.
- The IACUC approved a temporary cage size exemption for 1 animal that gained weight during quarantine, and because of quarantine, he could not be moved to a different room with larger caging.

**Justification for and Extent of Watering Exceptions:**

- There is an IACUC approved protocol for up to 4 rhesus macaques to have water control to ensure motivation to perform tasks during testing. During this reporting period, 1 animal was on water control. There are other IACUC approved protocols for up to 29 rhesus macaques to have water control to ensure motivation to perform tasks during testing. During this reporting period, 6 animals were on water control

**Justification for and Extent of the Use of Gestation Crates:**

- There is an IACUC approved protocol for up to 45 swine to be housed for six months or less in gestation crates for the controlling of dietary intake and physical activity.

**Justification for and Extent of the Water and Food Exceptions:**

- There is an IACUC approved protocol for up to 2 rhesus macaques to have water control to ensure motivation to perform a research task.
- There is an IACUC approved protocol for up to 5 rhesus macaques to have water and food control to ensue motivation to perform a research task.

**Justification for and Extent of Caging:**

- There is an IACUC approved protocol to allow for up to 100 sheep to be held in a cage while undergoing Letrozol studies. Animals can lie down and stand up comfortably, and caging is for 14 days or less.

## NIH Policy on Allowable Costs for Grant Activities Involving Animals when Terms and Conditions are not Upheld

**Notice Number:** NOT-OD-07-044

### Key Dates

Release Date: January 26, 2007

### Issued by

National Institutes of Health (NIH), (<http://www.nih.gov>)

The purpose of this Notice is to clarify that no costs for activities with live vertebrate animals may be charged to NIH if there is not a valid Animal Welfare Assurance and Institutional Animal Care and Use Committee (IACUC) approval. This notice is applicable to grants and cooperative agreements involving activities with live vertebrate animals.

### Background

Terms and conditions applicable to all grant awards that involve live, vertebrate animals - including research, research training, experimentation, biological testing, custom antibody preparation, or related purposes - require a valid Animal Welfare Assurance (Domestic, Foreign, or Inter-institutional Assurance, as applicable) approved by the NIH Office of Laboratory Animal Welfare (OLAW), and valid IACUC approval. IACUC approval must be dated within the last three years in order to be valid. IACUCs are not authorized to administratively extend approval beyond three years. Foreign grantees receiving direct support are not required to provide IACUC approval, but must have a valid Foreign Assurance on file with OLAW (see <http://grants.nih.gov/grants/olaw/assurance/500index.htm> for list of foreign institutions with approved Assurances).

### Policy

The Office of Management and Budget Cost Principles and the NIH Grants Policy Statement (NIHGPS) do not permit charges to grant awards for the conduct of animal activities during periods of time that the terms and conditions of the NIHGPS are not upheld. Specific situations under which charges are not allowable are:

1. The conduct of animal activities in the absence of a valid Assurance on file with OLAW.
2. The conduct of animal activities in the absence of valid IACUC approval of the activity. Absence of IACUC approval includes failure to obtain IACUC approval, expiration, or suspension of IACUC approval. Suspension is described in the PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy) at section IV.C.6. (<http://grants.nih.gov/grants/olaw/references/phspol.htm>)

Institutions are required to report such situations to the Institute/Center (IC) supporting the award. NIH expects grantees to continue to maintain and care for animals during the periods described above. Funding components may allow expenditure of NIH grant funds for maintenance and care of animals on a case-by-case basis.

Additionally, these situations constitute serious noncompliance with section IV.F.3. of the PHS Policy and as such must be promptly reported to OLAW in accord with the PHS Policy. See NOT OD-05-034, Guidance on Prompt Reporting to OLAW (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>)

Grantees are reminded that under consortium (subaward) agreements in which the grantee collaborates with one or more other organizations, the grantee, as the direct and primary recipient of NIH grant funds, is accountable for the performance of the project, the appropriate expenditure of grants funds by all parties, and all other obligations of the grantee as specified in the NIHGPS. The animal welfare requirements that apply to grantees also apply to consortium participants and subprojects. The prime grantee is responsible for including these requirements in its agreements with collaborating organizations, and for ensuring that all sites engaged in research involving the use of live vertebrate animals have an appropriate Animal Welfare Assurance and that the activity has a valid IACUC approval. (see <http://grants.nih.gov/grants/olaw/assurance/300index.htm> for a list of domestic institutions with Assurances). If the prime grantee does not

have an Animal Welfare Assurance and the animal work will be conducted at an institution with an Assurance, the grantee must obtain an Inter-institutional Assurance from OLAW. When the grantee is a domestic institution and there is a foreign performance site using animals, the grantee must ensure that the performance site has an appropriate Foreign Assurance and must provide verification of IACUC approval by the domestic grantee's IACUC, certifying to NIH that the activity as conducted at the foreign performance site is acceptable to the grantee. (See NIH GPS, Part II, Terms and Conditions of NIH Grant Awards, Consortium Agreements, [http://grants.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part12.htm#\\_Toc54600251](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part12.htm#_Toc54600251)).

## Inquiries

Questions concerning this Notice should be directed to:

Office of Policy for Extramural Research Administration  
National Institutes of Health  
Telephone: 301-435-0938  
Email: [grantspolicy@od.nih.gov](mailto:grantspolicy@od.nih.gov)

Questions about Assurances or IACUC approval of animal activities should be directed to:

Office of Laboratory Animal Welfare  
Division of Assurances  
National Institutes of Health  
Telephone: 301-496-7163  
Email: [olawdoa@mail.nih.gov](mailto:olawdoa@mail.nih.gov)

[Weekly TOC for this Announcement](#)  
[NIH Funding Opportunities and Notices](#)



Office of  
Extramural  
Research (OER)



National Institutes of  
Health (NIH)  
9000 Rockville Pike  
Bethesda, Maryland 20892



Department of Health  
and Human Services  
(HHS)



Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, RealPlayer, Video or Flash files, see [Help Downloading Files](#).

# Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals

**Notice Number:** NOT-OD-05-034

## Key Dates

Release Date: February, 24, 2005

## Issued by

Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research (<http://grants.nih.gov/grants/olaw/olaw.htm>)

This Notice provides guidance to Public Health Service (PHS) awardee institutions and Institutional Animal Care and Use Committees (IACUCs) on the prompt reporting requirements of the PHS Policy on Humane Care and Use of Laboratory Animals (Policy) (<http://grants.nih.gov/grants/olaw/references/phspol.htm>). This guidance is intended to assist IACUCs and Institutional Officials in determining what, when, and how situations should be reported under IV.F.3 of the Policy, and to promote greater uniformity in reporting. This Notice supersedes the January 12, 1994 Dear Colleague letter from the former Division of Animal Welfare, Office for Protection from Research Risks (now the Office of Laboratory Animal Welfare, or OLAW).

## Background

PHS Policy, IV.F.3, requires that:

"The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

- a) any serious or continuing noncompliance with this Policy;
- b) any serious deviation from the provisions of the *Guide [for the Care and Use of Laboratory Animals]* ; or
- c) any suspension of an activity by the IACUC."

IACUC suspensions of activities are cited at IV.C.6 and 7 of the Policy, and require a convened meeting of a quorum of the IACUC and the vote of a majority of the quorum present. The Institutional Official must review the reasons for suspension in consultation with the IACUC, take appropriate corrective action and report that action with full explanation to OLAW.

All institutions with Animal Welfare Assurances are required to comply with the provisions of IV.F.3. The Institutional Official signing the Assurance, in concert with the IACUC, is responsible for this reporting.

Reporting promptly to OLAW under IV.F.3 serves dual purposes. Foremost, it ensures that institutions deliberately address and correct situations that affect animal welfare, PHS-supported research, and compliance with the Policy. In addition, it enables OLAW to monitor the institution's animal care and use program oversight under the Policy, evaluate allegations of noncompliance, and assess the effectiveness of PHS policies and procedures.

The underlying foundation of the PHS Policy is one of institutional self-evaluation, self-monitoring and self-reporting. Public Law 99-158 (<http://grants.nih.gov/grants/olaw/references/hrea1985.htm>) requires that institutions be provided a reasonable opportunity to take corrective action before a grant or contract is suspended or terminated, and it is OLAW's role to assess whether the corrective actions reported by institutions under IV.F.3 are adequate. OLAW will assist the reporting Institution in developing definitive corrective plans and schedules if necessary. Compliance actions affecting an award are rare because institutions are usually able to address incidents successfully and take appropriate actions to prevent recurrence.

## Guidance on Prompt Reporting

A comprehensive list of definitive examples of reportable situations is impractical. Therefore, the examples below do not cover all instances but demonstrate the threshold at which OLAW expects to receive a report. Institutions should use rational judgment in determining what situations meet the provisions of IV.F.3 and fall within the scope of the examples below, and consult with OLAW if in doubt. OLAW welcomes inquiries and discussion and will provide guidance with regard to specific situations. Situations that meet the provisions of IV.F.3 and are identified by external entities such as the United States Department of Agriculture or the Association for

Assessment and Accreditation of Laboratory Animal Care International, or by individuals outside the IACUC or outside the institution, are not exempt from reporting under IV.F.3.

Examples of reportable situations:

- conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals;
- conduct of animal-related activities without appropriate IACUC review and approval;
- failure to adhere to IACUC-approved protocols;
- implementation of any significant change to IACUC-approved protocols without prior IACUC approval as required by IV.B.7.;
- conduct of animal-related activities beyond the expiration date established by the IACUC (note that a complete review under IV.C is required at least once every three years);
- conduct of official IACUC business requiring a quorum (full Committee review of an activity in accord with IV.C.2 or suspension in accord with IV.C.6) in the absence of a quorum;
- conduct of official IACUC business during a period of time that the Committee is improperly constituted;
- failure to correct deficiencies identified during the semiannual evaluation in a timely manner;
- chronic failure to provide space for animals in accordance with recommendations of the *Guide* unless the IACUC has approved a protocol-specific deviation from the *Guide* based on written scientific justification;
- participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained as required by IV.C.1.f;
- failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures);
- failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);
- failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO<sub>2</sub>);
- failure of animal care and use personnel to carry out veterinary orders (e.g., treatments); or
- IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the *Guide*, or the institution's Animal Welfare Assurance.

OLAW recognizes that there may be levels of morbidity and mortality in virtually any animal-related activity, including those associated with the care and use of animals in research, testing, and teaching that are not the result of violations of either the Policy or the *Guide*. OLAW offers the following examples of situations which may *not* meet the threshold for reporting, based on consideration of the circumstances by the IACUC.

Examples of situations *not* normally required to be reported:

- death of animals that have reached the end of their natural life spans;
- death or failures of neonates to thrive when husbandry and veterinary medical oversight of dams and litters was appropriate;

- animal death or illness from spontaneous disease when appropriate quarantine, preventive medical, surveillance, diagnostic, and therapeutic procedures were in place and followed;
- animal death or injuries related to manipulations that fall within parameters described in the IACUC-approved protocol; or
- infrequent incidents of drowning or near-drowning of rodents in cages when it is determined that the cause was water valves jammed with bedding (frequent problems of this nature, however, *must* be reported promptly along with corrective plans and schedules).

#### Time Frame for Reporting

Institutions should notify OLAW of matters falling under IV.F.3 promptly, i.e., without delay. Since IV.F.3 requires a full explanation of circumstances and actions taken and the time required to fully investigate and devise corrective actions may be lengthy, OLAW recommends that an authorized institutional representative provide a preliminary report to OLAW as soon as possible and follow-up with a thorough report once action has been taken. Preliminary reports may be in the form of a fax, email, or phone call. Reports should be submitted as situations occur, and not collected and submitted in groups or with the annual report to OLAW.

#### Information to Be Reported

Include as many of the following items of information as possible in the initial contact with OLAW. A follow-up report may address anything not known at the time of the initial report and should summarize the institution's corrective action. If a long term plan is necessary, describe the plan and include a reasonable schedule. This information will allow OLAW to assess the circumstances and actions taken to correct and prevent recurrence of the situation.

Information to be included:

- Animal Welfare Assurance number (<http://grants.nih.gov/grants/olaw/assurance/300index.htm>);
- relevant grant or contract number(s) if the situation is related to an activity directly supported by PHS;
- a full description of any potential or actual affect on PHS-supported activities if the situation is not directly supported by the PHS but is in a functional, programmatic, or physical area that could affect PHS-supported activities (e.g., inadequate program of veterinary care, training of technical/husbandry staff, or occupational health; inadequate sanitation due to malfunctioning cage washer; room temperature extremes due to HVAC failures);
- full explanation of the situation, including what happened, when and where, the species of animal(s) involved, and the category of individuals involved (e.g., principal or co-principal investigator, technician, animal caretaker, student, veterinarian, etc.);
- description of actions taken by the institution to address the situation; and
- description of short- or long-term corrective plans and implementation schedule(s).

Preliminary and final reports should be made to:

Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982  
Phone: 301-594-2061  
FAX: 301-402-2803  
E-mail: [olawdco@mail.nih.gov](mailto:olawdco@mail.nih.gov)

#### Inquiries

JAN 04 2010

For questions or further information, contact:

Director, Office of Laboratory Animal Welfare  
Office of Extramural Research,  
Office of the Director, National Institutes of Health  
RKL 1, Suite 360  
6705 Rockledge Dr.  
Bethesda, MD 20892-7982  
(For express or hand-delivered mail use zip code 20817)  
Telephone (301) 496-7163  
[olaw@od.nih.gov](mailto:olaw@od.nih.gov)

Weekly TOC for this Announcement  
NIH Funding Opportunities and Notices



Office of  
Extramural  
Research (OER)



National Institutes of  
Health (NIH)  
9000 Rockville Pike  
Bethesda, Maryland 20892



Department of Health  
and Human Services  
(HHS)



**Note:** For help accessing PDF, RTF, MS Word, Excel, PowerPoint, RealPlayer, Video or Flash files, see [Help Downloading Files](#).

SEP 30 2009

# From Bench to Bedside

## Academia slows the search for cures.

BY SHARON Bogley

**N**OW THAT PRESIDENT Obama has almost all of his top science picks in place—from the Department of Energy to the FDA—the lack of an appointee for director of the National Institutes of Health is

standing out like a creationist at an evolution conference. I hope the delay means Obama has grasped the need for, and the difficulty of finding, a powerful director who can get beyond the rhetoric about moving discoveries out of the lab and make it a reality. That hasn't happened yet, six years after a much-ballyhooed NIH "road map" declared such bench-to-bedside research a priority and vowed to reward risk-taking, innovative studies, not the same old incremental research that has produced too few cures.

NIH has its work cut out for it, for the forces within academic medicine that (inadvertently) conspire to impede research aimed at a clinical payoff show little sign of abating. One reason is the profit motive, which is supposed to induce pharma and biotech to invest in the decades-long process of discovering, developing and testing new compounds. It often does. But when a promising discovery has the profit potential of *Pets.com*, patients can lose out. A stark example is the work of Donald Stein, now at Emory University, who in the 1960s noticed that female rats recovered from head and brain injuries more quickly and completely than male rats. He hypothesized that the pregnancy hormone progesterone might be the reason. But progesterone is not easily patentable. Nature already owns the patent, as it were, so industry took a pass. "Pharma didn't see a profit potential, so our only hope was to get NIH to fund the large-scale clinical trials," says Stein. Unfortunately, he had little luck getting NIH support for his work (more on that later) until 2001, when he

received \$2.3 million for early human research, and in October a large trial testing progesterone on thousands of patients with brain injuries will be launched at 17 medical centers. For those of you keeping score at home, that would be 40 years after Stein made his serendipitous discovery.

The desire for academic advancement, perversely, can also impede bench-to-bedside research. "In order to get promoted, a scientist must publish in prestigious journals," notes Bruce Bloom,

president of Partnership for Cures, a philanthropy that supports research.

The incentive is to publish and secure grants instead of to create better treatments and cures.

And what do top journals want? "Fascinating new scientific knowledge, [not] mundane treatment discoveries," he says. Case in point: in research supported by Partnership for Cures, scientists

led by David Teachey of Children's Hospital of Philadelphia discovered that rapamycin, an immune-suppressing drug, can vanquish the symptoms of a rare and sometimes fatal children's disease called ALPS, which causes the body to attack its own blood cells. When Teachey developed a mouse model to test the treatment, he published it in the top hematology journal, *Blood*, in 2006. But the 2009 discovery that rapamycin can cure kids with ALPS? In the 13th-ranked journal. The hard-core science was already known, so top journals weren't interested in something as trivial as curing kids. "It would be nice if this sort of work were more valued in academia and top journals," Teachey says. Berish Rubin of Fordham University couldn't agree more. He discovered a treatment for a rare, often fatal genetic disease, familial dysautonomia. Given the choice of publishing in a top journal, which would have taken months, or in a

lesser one immediately, he went with the latter. "Do I regret it?" Rubin asks. "Part of me does, because I'm used to publishing in more highly ranked journals, and it's hurt me in getting NIH grants. But we had to weigh that against getting the information out and saving children's lives."

Not all scientists put career second. One researcher recently discovered a genetic mutation common in European Jews. He has enough to publish in a lower-tier journal but

is holding out for a top one, which means identifying the physiological pathway by which the mutation leads to disease. Result: at least two more years before genetic counselors know about the mutation and can test would-be parents and fetuses for it.

With these forces in play, NIH has to push back even harder to make translational research a

**When a promising discovery has no profit potential, patients can lose out.**

priority. When Stein applied for NIH funding in the 1980s and 1990s, "people didn't believe that a pregnancy hormone could help patients recover from brain injury," he says. "People said it was too simple." And when he, too, tried to publish in top journals, the papers were rejected in large part because all he was reporting was success in treating people, not the mechanism or physiological pathway that constitutes the sexy science that wins plaudits. Teachey could not get NIH funding either. Reviewers said the work was too translational—and this was *after* the NIH road map professed love for translational research. It will take an NIH director of almost mythic proportions to turn around this ship.

Bogley is NEWSWEEK's science editor. She told me privately that she's smarter than everybody else in the office. That should make for an awkward company picnic! —S.C.

PHOTO: GETTY IMAGES

## Major SAEN Victory

*Thank you!*

**-- USDA cites the University of Wisconsin for AWA Violations  
-- Second Complaint already filed**

An official complaint filed by Stop Animal Exploitation NOW! on February 16, 2009, against the University of Wisconsin, Madison (UW) has claimed a victory for the primates at UW. The USDA investigation conducted in April of 2009 cited UW for inadequate primary enclosures.

The complaint culminated from SAEN's research which discovered an incident at UW involving extreme negligence and serious violations of the Animal Welfare Act (AWA) which directly affected several primates named Glen, Shepard, and Aldrin. UW records for 6/29/07 disclose that Glen escaped from his cage and severely injured both Aldrin and Shepard. Shepard sustained a large laceration across the palm of his right hand, while Aldrin's traumatic hand injury necessitated the amputation of a finger.

Even after this victory, SAEN is keeping the pressure on UW with a second official complaint being filed in March, demanding that severe action be taken against the same Madison lab in the case of Wally, a macaque monkey, who has suffered terribly for over a year.

Wally experienced many of the same traumas as other UW primates including self-inflicted injuries due to the psychological stress of being caged alone. He is part of an experiment where a portion of his skull is removed to expose his brain so that microelectrodes can be forced directly into it through cylinders which are bolted onto his skull. Records indicate that he was treated with a strong antibiotic, Doxycycline, for a bacterial brain infection which is very common in this type of experiment. We also know from the records that Wally is often immobilized in a primate restraint chair, a box-like device, used to severely restrict his movement.

The most detailed and troubling information in Wally's record chronicles his ongoing agony for a 9 day period in November of 2006.

On 11/5/06:

9:30 am "According to Care Staff he rejected food . . . To me he seems confused, significant pale color of face, but still active."

12:30 pm "Care staff reported that Wally is laying down in the cage."

5:00 pm "Wally is depressed, sitting on cage floor with hunched posture."

6:40 pm "Wally is alert, mobile, no interest in treats, prefers a 'head-down rump-up posture' . . . Headache?"

The next day is no better for Wally.

11/8/06 "Alert Mobile, sitting in head down rump up position. He has received pain medication and antibiotics, but they don't seem to be helping."

His suffering continues on . . . . .

11/7/06 "Still depressed. Sitting on cage floor with head down."



These entries paint a picture of a primate who is suffering terribly. The bacterial brain abscess which arose in April is still present seven months later. His condition has clearly deteriorated, and he is in excruciating pain. A few weeks later, his condition is so critical that a gravely concerned UW vet recommends euthanasia:

"As you know, Wally has been on continuous antibiotic therapy for some time now due to a brain abscess. . . . (first week of November, 2006), he started to display clinical signs of headache and illness, including depression, slumped/head-down posture and inappetence. . . . Due to the brain abscess and the need for permanent treatment, it may be advisable to make plans to humanely euthanize Wally sometime in the next several months, and replace him on study."

The last entry that we have for Wally is in early 2008 stating that he is still on antibiotics. More than 14 months after the UW veterinarian recommended euthanasia for Wally, he is still being used in experimentation despite a lingering bacterial infection. Wally's life has been one of abject suffering, loneliness, and pain.

*inexcusable*

1081-B St. Rt. 28 **PMB 280**

**Milford, Ohio 45150**

**513-575-5517**

**[www.saenonline.org](http://www.saenonline.org)**

Dr. Elizabeth Goldentyer

2/16/09

USDA/APHIS/AC

920 Main Campus Drive, Suite 2000

Raleigh, NC 27606

Dr. Goldentyer,

I am contacting you today in reference to the University of Wisconsin, Madison. I have recently received documentation (attached) which includes the health care records for several primates. These records reveal several violations in the areas of inadequate veterinary care, inadequate enclosures, and improperly trained personnel.

The record for the primate named Conrad reveal that this animal has suffered from a long series of bacterial infections and abscesses. The most serious issue relates to a deep tooth abscess that was first suspected on 10/17/06. This condition is again mentioned on 11/13/06 when the record suggests that further assessment be done, including an x-ray to discover the condition of the jaw. This condition is not discussed again until 1/22/07 when the record discusses a "chronic sore L Lower Jaw. Can palpate bone damage under lesion. Suspect deep tooth abscess with mandible damage. Tooth extraction, surgical repair recommended." No tooth extractions were performed until 2/5/07. Clearly, this animal was allowed to suffer unnecessary pain due to an untreated tooth abscess that was allowed to progress to a point where the mandible was damaged.

The records for the primates named Aldrin and Shepard discuss the escape of another primate (Glen) on 6/29/07. During this escape both Aldrin and Shepard were severely injured by Glen. Shepard's record reveals that he had a "large laceration on R palm – extending from between the 3<sup>rd</sup> & 4<sup>th</sup> finger to the wrist." Aldrin's record states that his hand received "major trauma, unable to repair. Amputated finger at 1<sup>st</sup> phalangeal/metacarpal joint."

It is very surprising that Glen's record for the relevant period does not even mention that he escaped.

Shepard's record also reveals that during a surgical procedure on 7/24/07 UW staff "Accidentally burned his forehead with soldering iron."

It is also clear that these animals would have experienced substantial pain and distress and should have been reported as such on the annual report filed by this facility.

It is very clear from this information that the primates at the University of Wisconsin do not receive adequate veterinary care, their enclosures are not adequate, or the staff are careless enough to leave them open allowing serious injuries to other animals. Additionally, the negligence that caused another primate to be burned during a surgical procedure is shocking.

I officially request that you initiate an immediate investigation of these incidents and that you levy the largest fine allowable by law against the University of Wisconsin, Madison.

I look forward to hearing from you in the near future about the fate of this facility.

Sincerely,

Michael A. Budkie, A.H.T.,

Executive Director, SAEN

Sec. 2.33 Attending veterinarian and adequate veterinary care.

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:

(1) The availability of appropriate facilities, personnel, equipment, and services to comply with the provisions of this subchapter;

(2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care;

-1/13/08, 1:15 p.m. a notation was made "no change in reluctance/inability to use right leg. History of similar neurologic or musculoskeletal disorder 2 years ago, will discuss further diagnostics and possible steroid treatment with PI" and 3:00 p.m. "Inability to use right leg due to arthritis or trauma?, stifle joint enlarged or relate to myopathy/neuropathy of 2 years ago, 1/15 blood work increased CPK- treatment options with PI".

-2/1/08: "spoke with PI, end studies, euthanize, not pursue extensive diagnostics per PI

-2/14/08: "very thin, poor muscle mass, prominent bones, poor prognosis, may require stomach tube, told PI may need to euthanize prior to 3/11/08 date; 10:50 a.m.: little voluntary movement, poor body condition <1.5; prominent vertebral column, pelvic bones, stifles

2/15/08: "generalized neuromuscular, metabolic disorder, bone marrow biopsy collected @ left humerus, Dr Capuano's Report: recommend euthanasia

2/18/08:4:50 p.m.: "Merde" still in lab for study purposes, will assess in morning"

2/20/08: 7:30 a.m.: "overall status same, no change in overall body condition"

Although treatment and observations were documented and an eventual diagnosis of a possible neurologic and/or musculoskeletal disorder was made, recommendations made by the attending veterinarian to the principal investigator (Dr. Basso) were not followed. According to interviews with veterinary staff, Dr. Basso was extremely uncooperative and reluctant to work with staff regarding the care of this animal. The IACUC eventually took action with this PI after another incident involving a different animal in June 2008 suspending Dr. Basso's animal privileges effective February 2009.

The following notations are from the complaint:

-"Wally"- #92039: there were numerous notations of bacterial infections involving the head cap starting 4/21/06. Antibiotic treatment was changed from Cephalexin to Doxycycline and continued daily through September 2009.

-11/28/06: attending veterinarian contacted PI (Dr. Van Kan) indicating "Wally" had been on continuous antibiotic treatment and after the "most recent regimen of Cephalexin....started to display clinical signs of headache and illness including depression, slumped/head-down posture and inappetance." The attending veterinarian recommended giving Doxycycline in order to keep "Wally's" symptoms under control and rotated with a new drug to prevent antimicrobial resistance. Recommendation to PI was also made to reevaluate "Wally" in the future for possible euthanasia based on his previous diagnosis of a possible brain abscess and need for permanent treatment, however, no further documentation was provided in the medical records as to why these recommendations were not followed or addressed.

Based on review of the IACUC minutes, protocols, animal records and interviews with staff, the animals were housed appropriately based on exemptions approved by the IACUC and not subjected to excessive amounts of time in chair apparatus as alleged in the complaint.

Although treatments and observations were well-documented, based on the notations in the animals' records it was determined adequate veterinary care had not been pursued in a timely manner. Based on these findings the complaint was found to be valid.

RECEIVED

SEP 30 2009

BY: \_\_\_\_\_



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Animal Care

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Suite 200  
Raleigh, NC 27606

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

June 27, 2007

Michael Budkie, A.H.T.  
SAEN  
1081-B St., Rt. 28 PMB 280  
Milford, OH 45150  
[saen@saenonline.org](mailto:saen@saenonline.org)

Dear Michael:

Thank you for your letter of 25 June, 2007, concerning the University of Wisconsin at Madison. Your concern has been issued number 07-207. Please refer to this number when inquiring about this concern.

Animal Care is the division of the U.S. Department of Agriculture (USDA) that is responsible for the enforcement of the Animal Welfare Act. The Act provides minimum standards for the humane care and use of animals at USDA licensed or registered facilities.

Animal Care inspectors conduct routine unannounced inspections at all USDA licensed and registered facilities to ensure that they are meeting or exceeding these minimum standards. Our inspectors also conduct searches for unlicensed facilities conducting regulated activities. We perform inspections and searches when necessary in response to valid concerns and complaints received from the public to ensure the well-being of the animals and compliance with the law. If violations are found, enforcement action appropriate for the circumstances will be initiated.

Please be assured that we will look into your concerns and take appropriate action if necessary.

Thank you for your interest in the welfare of these animals.

Sincerely,

Elizabeth Goldentyer, DVM  
Director, Eastern Region  
USDA, APHIS, 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



Jaime A  
Laureano/NC/APHIS/USDA  
06/27/2007 08:49 AM

To Dawn E Barksdale/WI/APHIS/USDA  
cc Cathy F Hovancsak/MN/APHIS/USDA, Joseph A  
Nelson/NC/APHIS/USDA  
bcc  
Subject Complaint 07-207

Dawn,

Good morning. Here is complaint 07-207. The complaint is listed in the e-mail below and the complaint form is attached.

Jaime A. Laureano, ILA  
USDA/APHIS/AC Eastern  
(919) 855-7103

Betty J Goldentyer/NC/APHIS/USDA

<saen@saenonline.org>@inter2@gw

06/25/2007 11:52 PM

To Betty J Goldentyer/NC/APHIS/USDA@USDA  
cc  
Subject Official Complaint

Stop Animal Exploitation NOW!

1081-B St. Rt. 28 PMB 280  
Milford, Ohio 45150  
saen@saenonline.org 513-575-5517

Dr. Elizabeth Goldentyer  
6/25/07

USDA/APHIS/AC

920 Main Campus Drive

Suite 2000

Raleigh, NC 27606

Dr. Goldentyer,

I am contacting you regarding a matter of the utmost urgency and importance. I have recently obtained documents from the laboratory at the University of Wisconsin, Madison. These documents raise serious doubts as to adherence to Animal Welfare Act (AWA) regulations by the staff of this facility. Therefore I am lodging an Official Complaint against this facility and I am requesting that you initiate an investigation immediately.

This complaint lists the specific animals with reference to which section of the AWA the documentation reveals violations.

A 4 year old female crab eating macaque monkey (cy0122) who died on 11/3/05 was found to have foreign body lodged in the intestinal tract. This object had been in place long enough to have caused tissue necrosis. This incident may be a violation of Sec. 2.33 Attending veterinarian and adequate veterinary care. (3) Daily observation of all animals to assess their health and well-being; Adequate veterinary assessment of this primate should have revealed the presence of this foreign object. The presence of " . . . 20 cc of a light red, clear, serous fluid" and a "6 cm rent" in the intestinal tract should have been diagnosed. Apparently this situation existed for a significant period of time because the small intestine had "multi-focal, transmural necrosis." Similarly, a 1 year old female marmoset (cj1146) was euthanized on 7/13/05. This animal is described as: "The left leg is mildly, diffusely swollen with the subcutis being thickened, gelatinous and glistening (edema). The left quadriceps muscle has a 2 mm, circular hole surrounded by moderate hemorrhage on the distal lateral portion. A hard sharp material slightly protrudes from the opening (fractured bone, presumptive." This marmoset had a tibial fracture and later developed an epiphyseal fracture as well. Proper preventative care and treatment after the initial fracture should have prevented the second fracture. This is clearly another incident of a violation of Sec. 2.33 Attending veterinarian and adequate veterinary care. Additionally, a female rhesus monkey (r87095) apparently died of "peritoneal and uterine rupture during delivery with subsequent sepsis. The sepsis was most likely the cause of death of this animal." Again, adequate veterinary observation should have prevented the development of sepsis. Clearly, the veterinary staff should have been aware of this monkey's pregnancy and should have been observing her closely enough to have been able to prevent sepsis. A 14 year old female rhesus monkey (r90153) died on 4/6/05. This monkey is described: "The second cartilaginous tracheal ring is focally broken with incomplete perforation of the tracheal wall. Approximately 2ml of blood mixed with froth is present in the upper half of the trachea. All the lung lobes are collapsed and have multifocal extensive hemorrhage." The cause of this situation is said to be "Trauma caused during intubation." This incident clearly demonstrates negligence on the part of UW Madison staff, and demonstrates the utilization of potentially unqualified personnel which is a violation of: Sec. 2.32 Personnel qualifications: (a) It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel. A 22 year old female rhesus monkey (r82062) died on 10/26/04 with a "Severe focal cerebral excavation, with

mild multifocal surrounding parenchymal fibrosis, left parietal lobe, brain." And "The cerebral excavation was most likely secondary to liquefactive necrosis post-headcap placement." This is clearly another incident of a violation of Sec. 2.33 Attending veterinarian and adequate veterinary care. Rhesus Monkey r94075, who is classified as an experimental death, died with "Severe multifocal chronic tract formation with fibrosis and mild multi-focal chronic meningitis and choroid plexitis, cerebrum, hypothalamus, meninges." This animal represents another incident of a violation of Sec. 2.33 Attending veterinarian and adequate veterinary care. Three marmosets cj0549, cj0475 and cj0543 are all listed with serious skin conditions such as: "Severe focally extensive full thickness necrosis with regionally extensive mild subacute paniculitis, skin (implant site). Marmoset cj0549 is also listed as "On the back over the mid-spine is a 5 mm long, full thickness skin wound from which one end of a 2 cm capsular implant protrudes." Clearly these primates suffered severely as a result of the experimentation in which they were used as did all of the primates listed in this complaint. However, the University of Wisconsin does not report any primates as being used in potentially painful or stressful experimentation without anesthesia. It is obvious that these animals experienced pain/distress, and yet no primates are reported in Column E for the UW, Madison. This is a clear violation of Sec. 2.36 Annual report. b) The annual report shall: (7) State the common names and the numbers of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used shall be attached to the annual report; Many other primates fall into this category as well. For example, rhesus monkey r01033 who had "Severe multifocal to coalescing chronic active pneumonia . . ." and r01035 who also had "Severe diffuse chronic active pneumonia . . ."

Due to the information contained in the necropsy reports listed above, I would also like to request that all experimental protocols involving the placement of headcaps or spinal implants be investigated, as well as the health and monitoring of all primates used in these protocols. These projects should be investigated thoroughly, with regard to all aspects of the Animal Welfare Act.

It is clear that the documentation for the animals listed above indicate a widespread pattern of negligence, inadequate veterinary care, and deceitful reporting of experimental procedures at the University of Wisconsin, Madison. All of these issues After examining the animals and procedures at this facility I am confident that your regulatory staff will find substantial AWA violations. I request that you immediately implement proceedings to prosecute the University of Wisconsin, Madison to the fullest extent that the law allows.

I would also request that you provide me with the results of this investigation when it is completed.

Sincerely,

Michael A. Budkie,

A.H.T.,

Executive Director,

SAEN



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### Inspection Report

UNIVERSITY OF WISCONSIN-MADISON

Customer ID: 616

Certificate: 35-R-0001

Site: 001

ALL CAMPUS SITES

RESEARCH ANIMAL RESOURCES CTR.

DIRECTOR RESEARCH ANIMAL RESOURCES CENTER

Type: ROUTINE INSPECTION

Date: Mar-02-2010

MADISON, WI 53726

THIS WAS A FOCUSED INSPECTION INVOLVING THE TRANSPORTATION OF LARGE ANIMALS AT THE MEDICAL SCHOOL.

NO NON-COMPLIANT ITEMS WERE IDENTIFIED DURING THIS INSPECTION.

EXIT INTERVIEW CONDUCTED WITH THE CHIEF CAMPUS VETERINARIAN AND ASSOCIATE DIRECTOR, RESEARCH ANIMAL RESOURCE CENTER.

Prepared By:

*Dawn Barksdale DVM*  
DAWN E BARKSDALE, D V M    USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1062

Mar-02-2010

Received By:

(b)(6),(b)(7)c

Date:

Title:

Mar-02-2010

MAR 16 2010



### Inspection Report

UNIVERSITY OF WISCONSIN-MADISON

Customer ID: 616

Certificate: 35-R-0001

RESEARCH ANIMAL RESOURCES CTR.

Site: 001

DIRECTOR RESEARCH ANIMAL

ALL CAMPUS SITES

1710 UNIVERSITY AVENUE 396 ENZYME INST

Type: ROUTINE INSPECTION

MADISON, WI 53726

Date: Dec-17-2009

**2.31** (c) (3)

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

(c)(3) IACUC functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall:.....

.....The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, with reference to Subchapter A, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals.....

\*\*IACUC facility inspections and program reviews did not contain reasonable and specific plans for correcting deficiencies. The IACUC must include plans for correcting deficiencies and should also consider methods in the plan to prevent re-occurrence of the non-compliance.

Correct by: from this date forward

**2.31** (d) (1) (ii)

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

(d) IACUC review of activities involving animals..... (1) In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing;.....

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

\*\*Protocols #A01195, #A00810, #00664, #G00510, #V1296 contain painful procedures. There is nothing to indicate that the principal investigators had considered alternatives to potentially painful procedures that may cause more than momentary or slight pain and/or distress to the animals in the written narratives of these protocols.

Prepared By:

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DAWN E BARKSDALE, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1062

Dec-17-2009

Received By:

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Date:

Dec-17-2009



### Inspection Report

Correct by: From this date forward

2.31 (d) (1) (viii)

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

(d) IACUC review of activities involving animals. (1) In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing:..... Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements:

.....(viii) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures;.....

\*\*In Protocol V846 there has been an unexpected high mortality rate in gerbils attributed to anesthesia. This has not been reported to the veterinary staff or to the IACUC. The research staff was not adequately trained to report incidents of this nature.

Correct by: From this date forward

2.31 (d) (1) (ix)

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

(d)(1)Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements:.....

.....(ix) Activities that involve surgery include appropriate provision for pre-operative and post-operative care of the animals in accordance with established veterinary medical and nursing practices.....

\*\*Protocol V1296: Under this protocol dogs undergo major survival surgeries after which they may be expected to develop acute, terminal renal failure, which did occur in at least two dogs on the study. The post-operative care for these dogs, as approved in the protocol, calls for the administration of subcutaneous fluids to the dogs postoperatively instead of intravenous fluid therapy. This post-operative treatment is not in accordance with established veterinary medical practices, and the protocol contains no scientific justification for such a departure.

Correct by: From this date forward

2.31 (d) (7)

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

(7) If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any Federal agency funding that activity;.....

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### Inspection Report

\*\*Protocols L294, M1486, M1640 were suspended by the ACUC in February 2009, however, no notification was provided to APHIS by the Institutional Official regarding the reasons for suspension and the corrective actions that had been taken.

Correct by: January 10, 2010

**2.31 (e) (3)**

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

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

1. Review of Protocol #A01245: The protocol includes the administration of several substances by means of needle/syringe injection or with a novel medical device system. The description of the proposed use of the animals contains insufficient detail to follow exactly what procedures will be done to the animals from the beginning of the study until the study's conclusion.

2. Review of Protocol #A00810: The protocol studies cardiac electrical activity in swine. The narrative of this protocol refers to the following:

- a. Performing ablation of liver, kidney and lung as part of the study but includes no specific details.
- b. A statement about external stimulation of brain tissues but includes no specific details.
- c. The surgical training portion of the protocol is mentioned, however, there is an insufficient description of the proposed use of the animals for the training portion.

A proposal for animal use must contain a complete description of the proposed use of the animals so the IACUC can determine that the proposed activities meet the requirements outlined under 2.31 (d) (1).

Correct by: From this date forward

**2.32 (a)**

**PERSONNEL QUALIFICATIONS.**

(a) It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel.....

\*\*A technician was observed inadequately restraining a non-human primate in a squeeze cage requiring her to make several attempts to administer an anesthetic via syringe. It is the responsibility of the facility to ensure that animal care staff are properly trained and qualified to perform their duties.

Correct by: From this date forward

Prepared By: *Dawn Barksdale, DVM*  
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 Title:            VETERINARY MEDICAL OFFICER Inspector 1062

Date:  
Dec-17-2009

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### Inspection Report

2.33 (b) (1)

**ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.**

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include: (1) The availability of appropriate facilities, personnel, equipment, and services to comply with the provisions of this subchapter;

\*\*In Building O, Rooms 3244A & 3244B are used for major operative survival surgical procedures. The following items were identified in these rooms after having been cleaned following surgical procedures: 1. rusty base of IV stand and shelves/side bar of steel cart; 2. hair clippings on a table; 3. drips/splatter residue on wall; 4. excessive accumulation of dirt on air vents; 5. dark colored material on front drawers of anesthesia machine. These items can interfere with effective sanitation and may compromise aseptic procedures performed in this room. It is the responsibility of the facility to ensure appropriate facilities and equipment are available as set forth in this section in order to promote the health and well-being of the animals.

Correct by December 17, 2009

2.33 (b) (2)

**ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.**

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include: (2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care;

1. Use of Chemical grade compounds

a. A bottle with a label stating "saturated Potassium Chloride", (KCL) was noted in Building T, Rm142D. It was being used to euthanize swine under protocols #A00664, A00810, and A01195.

b. Protocol #A01245 calls for the administration of "Sodium Salicylate, USP grade from Sigma" to swine as part of the proposal for animal use. The approved proposal does not contain any scientific justification for the use of a chemical grade compound when pharmaceutical grade sodium salicylate for injection is available. Non pharmaceutical grade chemical compounds must only be used when veterinary or human pharmaceutical grade products are not available or for scientific reasons with the approval of the IACUC.

2. The following outdated drugs or medical supplies were identified in various locations of the facility as noted:

- a. Building I, Room109: Acetaminophen liquid, 1 oz bottle, #1, exp 11/09.
- b. Building M, Triple antibiotic ophthalmic, tube #1, exp 5/09.
- c. Building M, Room 232: Chlorhexidine solution, gallon bottle, #1, exp 6/09.
- d. Building J, Room 658: Betadine solution, gallon bottle, #1, exp 11/08; Betadine solution 32 oz bottle, #1 exp 11/06 and #1 exp 2/07; Ophthalmic lube, tube #2; exp 7/08; Lactated Ringers Solution bag 500 ml, #1, exp 4/09

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Dec-17-2009

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### Inspection Report

- e. Building J, Room 575: Cyprofloracin ophthalmic, tube #1, exp 9/02; Lubricant jelly tube, #1, exp 1/85
- f. Building F, Room 142: Furosamide, 50 ml bottle, #1, exp 7/09; Lidocaine, 100 ml bottle, #1, exp 8/07; Propofol, 50 ml bottle, #4, exp 11/1/08; Ketamine, 10 ml bottle, #2, exp 4/08; Dexamethasone 4 mg/ml, 30 ml bottle, #1, exp 11/08.
- g. Building O, Room 3244: Ophthalmic lube, tube #1, exp 3/08; Nexaband solution, #1, exp 12/01.
- h. Building O, Room 3243: Plastic bottle containing brown liquid that was labeled "Povidone Iodine Solution" that did not include the exp date of the contents of the bottle.
- i. Building O, Room 243: 3.0 Maxon suture packets, #12, exp 5/09; Red top tubes, #75, exp 9/08; Sterile water for injection, 10 ml bottle, #1, exp 2/1/08,
- j. Building T, Room 142D: Sterile water for injection, 20 ml bottle, #1, exp 3/07; Halothane 250 ml bottles, #1 exp 1/04, #1 exp 3/08, #1 exp 5/09; Isoflurane 250 ml bottles, #2, exp 7/08; Pentothal 1 gm bottles, #3, exp 9/1/06; Fentanyl, 50 ml bottle, #1, exp 9/1/06; Omnipaque contrast agent, 50 ml bottles, #1 exp 10/21/06, #1 exp 7/3/09; Lactated Ringers Solution bag 1000 ml, #8 exp 1/1/07, #3 exp 7/07; 0.9% Sodium Chloride bag 1000 ml, #2 exp 5/09

The use of outdated medications may not be safe or efficacious and is not considered an acceptable standard of veterinary practice. The IACUC and attending veterinarians need to address this issue.

Correct by: From this date forward.

**2.33 (b) (3) DIRECT NCI**  
**ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.**

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:..... (3) Daily observation of all animals to assess their health and well-being; Provided, however, That daily observation of animals may be accomplished by someone other than the attending veterinarian; and Provided, further, That a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian.....

1. In Building P, Room 310B the following was observed: Gerbil #1 was thin with sunken flanks, had difficulty breathing with some open mouthed breathing; was wobbly and weak having been unrecognized by facility personnel. Necropsy findings revealed; "that this animal had a body condition score of 1 out of 5, the subcutis had negligible body fat and the thoracic cavity contained moderately abundant red watery pleural effusion."

2. Review of medical records for dogs #BDW8, #SRS-6, and TJK-7 on Protocol #V01296 revealed the following: All of these dogs had a major operative procedure as described in the proposal. Post-operatively dog #BDVW8's medical records contained notations that it had sub-mandibular, cervical and facial edema; #SRS-6's medical records stated this dog was not eating, was vomiting, very depressed, had edema and not producing urine; TJK-7's medical records stated this animal was very depressed, vomiting and not producing urine. There was no documentation in the animals' medical records that the changes observed in the dogs' condition were conveyed to the attending veterinarian for evaluation and assessment.

It is the responsibility of the research facility and research staff to have a mechanism of direct and frequent

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 DAWN E BARKSDALE, D V M      USDA, APHIS, Animal Care      Date: Dec-17-2009  
 Title: VETERINARY MEDICAL OFFICER Inspector 1062

Received By: \_\_\_\_\_  
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### Inspection Report

communication to ensure that problems of animal health and/or behavior are conveyed in a timely manner to the attending veterinarian for evaluation and assessment to ensure the health and well-being of the animals.

Correct by: From this day forward

**3.2 (b)**

**INDOOR HOUSING FACILITIES.**

(b) Ventilation. Indoor housing facilities for dogs and cats must be sufficiently ventilated at all times when dogs or cats are present to provide for their health and well-being, and to minimize odors, drafts, ammonia levels, and moisture condensation.....

1. Building O, Room 2429: Two dogs were being housed in this room at the time of the inspection. There was a strong odor of dog urine noted immediately upon entering the room. The enclosures did not contain urine or feces, the unoccupied enclosures in the room were clean, and there was no obvious source of the strong odor. Indoor housing facilities must be sufficiently ventilated to minimize odors. The facility needs to assess the ventilation system servicing this room to provide for the health and well-being of the dogs.

Correct by December 17, 2009

**3.11 (c)**

**CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL.**

(c) Housekeeping for premises. Premises where housing facilities are located, including buildings and surrounding grounds, must be kept clean and in good repair to protect the animals from injury, to facilitate the husbandry practices required in this subpart,.....

\*\*The air filters above the animal enclosures in Building A, Room K4/150 had an excessive accumulation of debris. No notation was found in the log to indicate the filters had been changed in the month of November. The filters should be cleaned and maintained in a manner to prevent the accumulation of debris in order to facilitate proper husbandry practices and promote the health and well being of the animals.

Correct by December 17, 2009

**3.75 (a)**

**HOUSING FACILITIES, GENERAL.**

....(a) Housing facilities for nonhuman primates must be designed and constructed so that they are structurally sound for the species of nonhuman primates housed in them. They must be kept in good repair.....

1. There were areas of flaking and peeling paint on the ceiling above occupied animal enclosures in Building L, Room L-144 and Building K, Rooms 428C and B11.

2. Building M, Room 251: The cover of a ceiling mounted light fixture above an occupied primary enclosure housing

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### Inspection Report

two animals was hanging down as a result of a broken clip, and water had accumulated inside the light fixture cover.

Correct by January 15, 2010.

**3.75 (e)**

**HOUSING FACILITIES, GENERAL.**

(e) Storage. Supplies of food and bedding must be stored in a manner that protects the supplies from spoilage, contamination, and vermin infestation. The supplies must be stored off the floor and away from the walls, to allow cleaning underneath and around the supplies. Food requiring refrigeration must be stored accordingly, and all food must be stored in a manner that prevents contamination and deterioration of its nutritive value. Only the food and bedding currently being used may be kept in animal areas, and when not in actual use, open food and bedding supplies must be kept in leakproof containers with tightly fitting lids to prevent spoilage and contamination. Substances that are toxic to the nonhuman primates but that are required for normal husbandry practices must not be stored in food storage and preparation areas, but may be stored in cabinets in the animal areas.....

1. There were open supplies of primate food not stored in a container with a tightly fitting lid to prevent spoilage and contamination in the SPF kitchen. There was a plastic bucket with a broken top containing marshmallows in the cabinet and an uncovered pan containing cut up pieces of fruit inside the walk-in refrigerator.
2. Cooling vests were stored inside the walk-in refrigerators on a shelf in two different refrigerators in Building L.
3. Employees in Building L were observed cutting primate diet with a spray bottle of cleaning liquid on the table next to where food was being prepared.
4. Building M, Room 337: Primate chow in bags was stored on a table directly against the walls.
5. Building L, SPF Kitchen: Cartons of fruit were stored on the floor of the walk-in refrigerator.

Supplies of food for primates should be stored in a manner to protect the food supplies from spoilage, contamination and vermin infestation. The facility needs to address this issue of food storage for the health and well-being of the primates.

Correct by December 17, 2009

**3.75 (f)**

**HOUSING FACILITIES, GENERAL.**

.....(f) Trash containers in housing facilities.....must have tightly fitted lids on them at all times.....

1. Building M: There were uncovered trash containers located in several primate testing rooms that did not have a tightly fitted lid. Per this section, there must be a tightly fitting lid present on trash containers in primate housing facilities at all times to minimize odors and disease hazards.

Correct by December 17, 2009

Prepared By: *Dawn Barksdale, DVM*  
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### Inspection Report

**3.80** (a) (2) (ii)

**PRIMARY ENCLOSURES.**

.....(a)(2) Primary enclosures must be constructed and maintained so that they: .....ii) Protect the nonhuman primates from injury.....

**\*\*Red rubber hoses are used to supply water to animals in Building M. One of the hoses on top of an enclosure housing 2 primates in Room 29 was missing pieces of the outermost layer of red rubber as a result of the animals picking at the hose.**

Primary enclosures should protect the animals from injury. Ingestion of foreign material can pose a hazard to the animals. This item was corrected by the facility during the inspection by replacing the damaged hose.

Corrected during the inspection

**3.84** (c)

**CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL.**

(c) Housekeeping for premises. Premises where housing facilities are located, including buildings and surrounding grounds, must be kept clean and in good repair in order to protect the nonhuman primates from injury, to facilitate the husbandry practices required in this subpart,.....

1. Building L, Room 109: Sides of the floor drain were dirty and had particulate debris and Betadine on its surface.
2. Building L, Hallway outside Room 119: Non-human primates are transferred to rolling cages while their home cages are cleaned and sanitized. The rolling cages are placed temporarily in the hallway until being returned to their home cages. The textured ceiling tiles in the hallway were dirty, and the ceiling was within reach of the non-human primates through the top of their temporary enclosures.
3. Building M, Room 16: Dirty ceiling mounted air filter.
4. Building L, Room 113: A leather restraint glove was located on the top of an occupied primary enclosure and was accessible to the animals.
5. Building M, Room 41: The housing room wall was dirty and had dried, dark colored spots/splashes on the upper wall in the back corner of room.

Primate housing areas must be kept clean and in good repair in order to protect the nonhuman primates from injury, and to facilitate the husbandry practices required in this subpart,

Correct by December 17, 2009

Prepared By: *Dawn Barksdale, DVM*  
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### Inspection Report

**3.125** (a)

**FACILITIES, GENERAL.**

(a) Structural strength. The facility must be constructed of such material and of such strength as appropriate for the animals involved. The indoor and outdoor housing facilities shall be structurally sound and shall be maintained in good repair to protect the animals from injury and to contain the animals.....

1. Building D, Holding Barn: Metal flashing on one of the corners of the holding barn had been damaged exposing jagged edges. The corner of the holding barn should be repaired in order to prevent injury to the animals housed in the area.

2. Building T, Room 115: The floor of one pen housing a large adult male pig was comprised of narrow slats/grate system. The animal's feet continually slid on the floor surface as he walked around the enclosure. The animal's feet slipped out from under him causing him to fall down several times. Other animals in the room were also observed to slide on the portion of their pens that had a solid concrete surface. The facility should be constructed in a manner that is structurally sound and maintained in a manner to protect the animals from injury as set forth in this section.

Correct by December 17, 2009

**3.131** (c)

**SANITATION.**

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

1. The wooden shelves in the feed/bedding storage room of Building J were not sealed or impervious to moisture. The unsealed surfaces could interfere with effective cleaning and sanitation of the shelving. The facility needs to address this issue.

2. Building J, Room 662: Facility personnel stated that investigator staff is responsible for cleaning the room after animals are moved out. Animals had been housed in this room and it had already been cleaned. There were wooden shavings and animal waste present on the shelves where the enclosures were placed, there was a thick layer of dust on various surfaces in the rooms, and the wall in the back corner of the room was dirty.

3. Building J, Room 663: Assorted equipment and cleaning implements were stored on the same shelf adjacent to primary enclosures housing regulated species.

4. Building J, Room 575: There was a thick layer of dust on the ceiling mounted air vent in the room that housed chinchillas and the ceiling surface next to the air vent was dirty.

5. Building O, Room 3243: There was dried blood on the outside surface of the drawers and on the wall adjacent to the sharps container in the room.

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Title: VETERINARY MEDICAL OFFICER Inspector 1062

Date:  
Dec-17-2009

Received By: \_\_\_\_\_  
CERTIFIED MAIL  
Title: 7009 0820 0000 9268 5075

Date:  
Dec-17-2009

01223077



### Inspection Report

UNIVERSITY OF WISCONSIN-MADISON

Customer ID: 616

Certificate: 35-R-0001

RESEARCH ANIMAL RESOURCES CTR.

Site: 001

DIRECTOR RESEARCH ANIMAL

ALL CAMPUS SITES

1710 UNIVERSITY AVENUE 396 ENZYME INST

Type: ROUTINE INSPECTION

MADISON, WI 53726

Date: Dec-09-2009

2.31 (c) (3)

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

(3)(c) IACUC functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall:.....

.....The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, with reference to Subchapter A, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals.....

\*\*IACUC facility inspections and program reviews did not contain reasonable and specific plans for correcting deficiencies. The IACUC must include plans for correcting deficiencies and should also consider methods in the plan to prevent re-occurrence of the non-compliance.

Correct by: from this date forward

2.31 (d) (1) (ii)

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

(d) IACUC review of activities involving animals..... (1) In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing:.....

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

\*\*Protocols #A01195, #A00810, #00664, #G00510, #V1296 contain painful procedures. There is nothing to indicate that the principal investigators had considered alternatives to potentially painful procedures that may cause more than momentary or slight pain and/or distress to the animals in the written narratives of these protocols.

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Date:  
Dec-10-2009

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### Inspection Report

Correct by: from this date forward

2.31 (d) (1) (viii)

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

(d) IACUC review of activities involving animals. (1) In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing:..... Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements:

.....(viii) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures;.....

\*\*In Protocol V846 there has been an unexpected high mortality rate in gerbils attributed to anesthesia. This has not been reported to the veterinary staff or to the IACUC. The research staff was not adequately trained to report incidents of this nature.

Correct by: From this date forward

2.31 (d) (1) (ix)

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

(d)(1)Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements:.....

.....(ix) Activities that involve surgery include appropriate provision for pre-operative and post-operative care of the animals in accordance with established veterinary medical and nursing practices.

\*\*Protocol V1296: Under this protocol dogs undergo major survival surgeries after which they may be expected to develop acute, terminal renal failure, which did occur in at least two dogs on the study. The post-operative care for these dogs, as approved in the protocol, calls for the administration of subcutaneous fluids to the dogs post-operatively instead of intravenous fluid therapy. This post-operative treatment is not in accordance with established veterinary medical practices, and the protocol contains no scientific justification for such a departure.

Correction: from this date forward

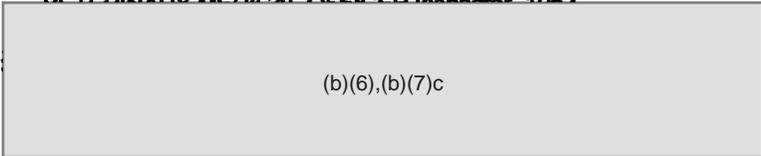
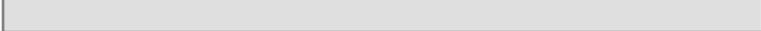
2.31 (d) (7)

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

(7) If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any Federal agency funding that activity,.....

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Date:  
Dec-10-2009



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\*\*Protocols L294, M1486, M1640 were suspended by the ACLIC in February 2009, however, no notification was provided to APHIS by the Institutional Official regarding the reasons for suspension and the corrective actions that had been taken.

Correct by: January 10, 2010

### 2.31 (e) (3)

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

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

1. Review of Protocol #A01245: The protocol includes the administration of several substances by means of needle/syringe injection or with a novel medical device system. The description of the proposed use of the animals contains insufficient detail to follow exactly what procedures will be done to the animals from the beginning of the study until the study's conclusion.
2. Review of Protocol #A00810: The protocol studies cardiac electrical activity in Swine. The narrative of this protocol refers to the following:
  - a. Performing ablation of liver, kidney and lung as part of the study but includes no specific details.
  - b. A statement about external stimulation of brain tissues but includes no specific details.
  - c. The surgical training portion of the protocol is mentioned, however, there is an insufficient description of the proposed use of the animals for the training portion.

A proposal for animal use must contain a complete description of the proposed use of the animals so the IACUC can determine that the proposed activities meet the requirements outlined under 2.31 (d) (1).

Correct by: From this date forward

### 2.32 (a)

#### PERSONNEL QUALIFICATIONS.

(a) It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel.....

\*\*A technician was observed inadequately restraining a non-human primate in a squeeze cage requiring her to make several attempts to administer an anesthetic via syringe. It is the responsibility of the facility to ensure that animal care staff are properly trained and qualified to perform their duties.

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Date:

Dec-10-2009

Received By:

(b)(6),(b)(7)c

Date:

Dec-10-2009

Title:





### Inspection Report

Correct by: From this date forward

2.33 (b) (1)

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include: (1) The availability of appropriate facilities, personnel, equipment, and services to comply with the provisions of this subchapter;

\*\*In Building O-Rooms 3244A & 3244B are used for major operative survival surgical procedures. The following items were identified in these rooms after having been cleaned: 1.rusty base of IV stand and shelves/side bar of steel cart; 2.hair clippings on a table; 3. drips/splatter residue on wall; 4. excessive accumulation of dirt on air vents; 5. dark colored material on front drawers of anesthesia machine. These items can interfere with effective sanitation and may compromise aseptic procedures performed in this room.

Correct by December 17, 2009

2.33 (b) (2)

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include: (2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care;

##### 1. Use of Chemical grade compounds

a. A bottle with a label stating saturated Potassium Chloride, (KCL) was noted in Building T- Rm142D. It was being used to euthanize swine under protocols #A00664, A00810, and A01195.

b. Protocol #A01245 calls for the administration of "Sodium Salicylate, USP grade from Sigma" to Swine as part of the proposal for animal use. The approved proposal does not contain any scientific justification for the use of a chemical grade compound when pharmaceutical grade sodium salicylate for injection is available. Non pharmaceutical grade chemical compounds must only be used when veterinary or human pharmaceutical grade products are not available or for scientific reasons with the approval of the IACUC.

##### 2. The following outdated drugs or medical supplies were identified in various locations of the facility as noted:

a. Building I-Room109: Acetaminophen liquid, 1 oz bottle, #1, exp 11/09.

b. Building M: Triple antibiotic ophthalmic, tube #1, exp 5/09.

c. Building M Room 232: Chlorhexidine solution, gallon bottle, #1, exp 6/09.

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(b)(6),(b)(7)c

Date:

Dec-10-2009

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### Inspection Report

- d. Building J Room 658: Betadine solution, gallon bottle, #1, exp 11/08; Betadine solution 32 oz bottle, #1 exp 11/06 and #1 exp 2/07; Ophthalmic lube, tube #2; exp 7/08; Lactated Ringers Solution bag 500 ml, #1, exp 4/09
- e. Building Room 575: Cyprofloxacin ophthalmic, tube #1, exp 9/02; Lubricant jelly tube, #1, exp 1/85
- f. Building F Room 142: Furosamide, 50 ml bottle, #1, exp 7/09; Lidocaine, 100 ml bottle, #1, exp 8/07; Propofol, 50 ml bottle, #4, exp 11/1/08; Ketamine, 10 ml bottle, #2, exp 4/08; Dexamethasone 4 mg/ml, 30 ml bottle, #1, exp 11/08.
- g. Building O Room 3244: Ophthalmic lube, tube #1, exp 3/08; Nexaband solution, #1, exp 12/01.
- h. Building O Room 3243: Plastic bottle containing brown liquid that was labeled "Povidone Iodine Solution" that did not include the exp date of the contents of the bottle.
- i. Building Room 243: 3.0 Maxon suture packets, #12, exp 5/09; Red top tubes, #75, exp 9/08; Sterile water for injection, 10 ml bottle, #1, exp 2/1/08,
- j. Building T Room 142D: Sterile water for injection, 20 ml bottle, #1, exp 3/07; Halothane 250 ml bottles, #1 exp 1/04, #1 exp 3/08, #1 exp 5/09; Isoflurane 250 ml bottles, #2, exp 7/08; Pentothal 1 gm bottles, #3, exp 9/1/06; Fentanyl, 50 ml bottle, #1, exp 9/1/06; Omnipaque contrast agent, 50 ml bottles, #1 exp 10/21/06, #1 exp 7/3/09; Lactated Ringers Solution bag 1000 ml, #8 exp 1/1/07, #3 exp 7/07; 0.9% Sodium Chloride bag 1000 ml, #2 exp 5/09

The use of outdated medications may not be safe or efficacious and is not considered an acceptable standard of veterinary practice. The IACUC and AVs need to address this issue.

Correct by: From this date forward.

**2.33 (b) (3) DIRECT NCI  
ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.**

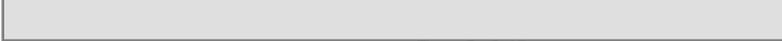
(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:..... (3) Daily observation of all animals to assess their health and well-being; Provided, however, That daily observation of animals may be accomplished by someone other than the attending veterinarian; and Provided, further, That a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian.....

1. Gerbil #1 housed in Building P Room 310B: was thin, sunken flank, difficulty breathing, wobbly, weak, some open mouthed breathing unrecognized by facility personnel. Necropsy findings revealed that this animal had a body condition score of 1 out of 5, the subcutis had negligible body fat and that the thoracic cavity contains moderately abundant red watery pleural effusion.

2. Review of Medical records for Dog #BDW8, #SRS-6, and TJG-7 on Protocol #V01296: All of these dogs had a major operative procedure as described in the proposal. Post-operatively Dog #BDVW8's medical records contained notations that it had sub-mandibular, cervical and facial edema, #SRS-6's medical records stated this dog was not eating vomiting and very depressed with edema not producing urine, TJG-7's medical records stated this animal was very depressed, vomiting with no urine. There was no documentation in the animals medical records that the changes observed in the dogs condition were conveyed to the attending veterinarian for evaluation and assessment.

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Date:  
Dec-10-2009

11/27/09



### Inspection Report

It is the responsibility of the research facility and research staff to have a mechanism of direct and frequent communication to ensure that problems of animal health and/or behavior are conveyed in a timely manner to the attending veterinarian for evaluation and assessment to ensure the health and well-being of the animals.

Correct: From this day forward

**3.2 (b)**

**INDOOR HOUSING FACILITIES.**

(b) Ventilation. Indoor housing facilities for dogs and cats must be sufficiently ventilated at all times when dogs or cats are present to provide for their health and well-being, and to minimize odors, drafts, ammonia levels, and moisture condensation.....

1. Building O Room 2429: Two Dogs were being housed in this room at the time of the inspection. There was a strong odor or dog urine noted immediately upon entering the room. The enclosures did not contain urine or feces, the unoccupied enclosures in the room were clean, and there was no obvious source of the strong odor.

Indoor housing facilities must be sufficiently ventilated to minimize odors. The facility needs to assess the ventilation system servicing this room to provide for the health and well-being of the dogs.

Correct by December 17, 2009

**3.11 (c)**

**CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL**

(c) Housekeeping for premises. Premises where housing facilities are located, including buildings and surrounding grounds, must be kept clean and in good repair to protect the animals from injury, to facilitate the husbandry practices required in this subpart,.....

\*\*The air filters above the animal enclosures in Building A, Room K4/150 had an excessive accumulation of debris. No notation was found in the log to indicate the filters had been changed in the month of November. The filters should be cleaned and maintained in a manner to prevent the accumulation of debris in order to facilitate proper husbandry practices and promote the health and well being of the animals.

Correct by December 17, 2009

**3.75 (a)**

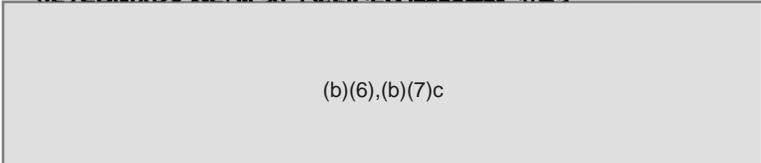
**HOUSING FACILITIES, GENERAL.**

....(a) Housing facilities for nonhuman primates must be designed and constructed so that they are structurally sound for the species of nonhuman primates housed in them. They must be kept in good repair.....

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Date:  
Dec-10-2009

(b)(6),(b)(7)c

9/10/09



### Inspection Report

1. There were areas of flaking and peeling paint on the ceiling above occupied NHP enclosures in Building L, Room L-144 and Building K Rooms 428C, K-B11.
2. Building M Room 251: The cover of a ceiling mounted light fixture above an occupied primary enclosure housing two NHP was hanging down as a result of a broken clip, and water had accumulated inside the light fixture cover.

Correct by January 15, 2010.

#### 3.75 (e)

##### HOUSING FACILITIES, GENERAL.

(e) Storage. Supplies of food and bedding must be stored in a manner that protects the supplies from spoilage, contamination, and vermin infestation. The supplies must be stored off the floor and away from the walls, to allow cleaning underneath and around the supplies. Food requiring refrigeration must be stored accordingly, and all food must be stored in a manner that prevents contamination and deterioration of its nutritive value. Only the food and bedding currently being used may be kept in animal areas, and when not in actual use, open food and bedding supplies must be kept in leakproof containers with tightly fitting lids to prevent spoilage and contamination. Substances that are toxic to the nonhuman primates but that are required for normal husbandry practices must not be stored in food storage and preparation areas, but may be stored in cabinets in the animal areas.....

1. There were open supplies of NHP food not stored in a container with a tightly fitting lid to prevent spoilage and contamination in the SPF kitchen. There was a plastic bucket with a broken top containing marshmallows in the cabinet and an uncovered pan containing uncovered pieces of fruit inside the walk-in refrigerator.
2. Cooling vests were stored inside the walk-in refrigerators on a shelf in two different refrigerators in Building L
3. Employees in Building L were observed cutting NHP diet with cleaning compound on the table where food was being prepared.
4. Building M Room 337: Primate chow in bags was stored on a table directly against the walls.
5. Building L-SPF Kitchen: Cartons of fruit were stored on the floor of the walk-in refrigerator

Supplies of food for NHP's should be stored in a manner to protect the food supplies from spoilage, contamination and vermin infestation. The facility needs to address this issue of food storage for the health and well-being of the primates.

Correct by December 17, 2009.

#### 3.75 (f)

##### HOUSING FACILITIES, GENERAL.

.....(f) Trash containers in housing facilities.....must have tightly fitted lids on them at all times.....

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Date:  
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Received By: (b)(6),(b)(7)c

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Date:  
Dec-10-2009



### Inspection Report

1. Building M: There were uncovered trash containers located in several NHP testing rooms that did not have a tightly fitted lid. Per this Section, there must be a tightly fitting lid present on trash containers in NHP housing facilities at all times to minimize odors and disease hazards.

Correct by December 17, 2009

**3.80** (a) (2) (ii)

**PRIMARY ENCLOSURES.**

.....(a)(2) Primary enclosures must be constructed and maintained so that they: .....ii) Protect the nonhuman primates from injury.....

1. Red rubber hoses are used to supply water to NHPs in Building M. One of the hoses on top of an enclosure housing 2 primates in Room 29 was missing pieces of the outermost layer of red rubber as a result of the NHPs picking at the hose.

Primary enclosures should protect the NHPs from injury. Ingestion of foreign material can pose a hazard to the animals. This item was corrected by the facility during the inspection by replacing the damaged hose.

Corrected during the inspection

**3.84** (c)

**CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL.**

(c) Housekeeping for premises. Premises where housing facilities are located, including buildings and surrounding grounds, must be kept clean and in good repair in order to protect the nonhuman primates from injury, to facilitate the husbandry practices required in this subpart,.....

- 1. Building L Room 109: Sides of the floor drain were dirty and had particulate debris and Betadine on its surface.
- 2. Building L Hallway outside Room 119: NHPs are transferred to rolling cages while their home cages are cleaned and sanitized. The rolling cages are placed temporarily in the hallway until being returned to their home cages. The textured ceiling tiles in the hallway were dirty, and the ceiling was within reach of the NHPs through the top of their temporary enclosures.
- 3. Building M Room 16: Dirty ceiling mounted air filter.
- 4. Building L Room 113: A leather restraint glove was on located on the top of an occupied primary enclosure and was accessible to the animals.
- 5. Building M Room 41: Housing room wall dirty and had dried dark colored spots/splashes on the upper wall in the

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Date:  
Dec-09-2009

Title: (b)(6),(b)(7)c

Received By: (b)(6),(b)(7)c  
Date:  
Dec-10-2009



### Inspection Report

back corner of room.

Primate housing areas must be kept clean and in good repair in order to protect the nonhuman primates from injury, and to facilitate the husbandry practices required in this subpart,

Correct by December 17, 2009

**3.125 (a)**

**FACILITIES, GENERAL.**

(a) Structural strength. The facility must be constructed of such material and of such strength as appropriate for the animals involved. The indoor and outdoor housing facilities shall be structurally sound and shall be maintained in good repair to protect the animals from injury and to contain the animals.....

1. Building D Holding Barn: Metal flashing on one of the corners of the holding barn had been damaged exposing jagged edges. The corner of the holding barn should be repaired in order to prevent injury to the animals housed in the area.

2. Building T Room 115: The floor of one pen housing a large adult male Pig was comprised of narrow slats/grate system. The animal's feet continually slid on the floor surface as it walked around the enclosure and the animal's feet slipped out from under the animal and it fell down several times. Other animals in the room were also observed to slide on the portion of their pens that had a solid concrete surface. The facility should be constructed in a manner that is structurally sound and maintained in a manner to protect the animals from injury as set forth in this section.

Correct by December 17, 2009

**3.131 (c)**

**SANITATION.**

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

1. The wooden shelves in the feed/bedding storage room of Building J were not sealed or impervious to moisture. The unsealed surfaces could interfere with effective cleaning and sanitation of the shelving. The facility needs to address this issue.

2. Building J Room 662: Facility personnel stated that investigator staff is responsible for cleaning the room after animals are moved out. Animals were housed in this room until 11/26/09 and had already been cleaned. Wooden

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Received By:       Date: Dec-10-2009  
 Title: (b)(6),(b)(7)c



### Inspection Report

UNIVERSITY OF WISCONSIN-MADISON

Customer ID: 616

Certificate: 35-R-0001

Site: 001

ALL CAMPUS SITES

RESEARCH ANIMAL RESOURCES CTR.

DIRECTOR RESEARCH ANIMAL RESOURCES CENTER

Type: ROUTINE INSPECTION

MADISON, WI 53726

Date: Oct-29-2009

This was a focused inspection involving the review of records at the Graduate School.

No non-compliant items were identified during this inspection.

Prepared By:

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Date:

Oct-29-2009

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Date:

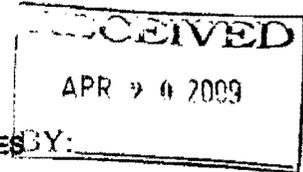
Oct-29-2009



### Inspection Report

UNIVERSITY OF WISCONSIN-MADISON  
RESEARCH ANIMAL RESOURCES CTR.  
DIRECTOR RESEARCH ANIMAL  
1710 UNIVERSITY AVENUE 396 ENZYME INST

Customer ID: 616  
Certificate: 35-R-0001  
Site: 001  
ALL CAMPUS SITES BY:



MADISON, WI 53726

Type: ROUTINE INSPECTION  
Date: Apr-09-2009

**3.80 (a) (2) (iii)**

**PRIMARY ENCLOSURES.**

(a) General requirements. ....

.....(2) Primary enclosures must be constructed and maintained so that they.....

.....(iii) Contain the nonhuman primates securely and prevent accidental opening of the enclosure, including opening by the animal;.....

**\*\*While reviewing records it was noted that non human primate RQ2653 was found on the morning of 6/29/2007 to have escaped from its enclosure and was loose in the animal room. Interactions between RQ2653 and two other caged animals resulted in the hand injuries of #R97097 (laceration to the right palm) and #00E106 (right index finger). It is the responsibility of the facility to ensure that the enclosures securely contain the non-human primates in order to promote the health and well-being of the animals as set forth in this section.**

**\*\*Records and interviews indicated that corrective procedures have been established to prevent animals from escaping. Personnel have been retrained in the proper handling and care of the animals housed in the facility.**

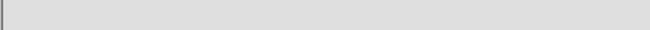
Correction: Ensure established procedures are properly followed.

This inspection was focused on nonhuman primates at the Medical School.

Inspection was conducted with the Associate Director, RARC, Chief Campus Veterinarian and other staff members.

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Date:  
Apr-09-2009

Title:   
Received:  (b)(6),(b)(7)c  
Title: 

Date:  
Apr-09-2009





United States Department of Agriculture  
Animal and Plant Health Inspection Service

**INSPECTION REPORT**

NOV 15 2008  
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**UNIVERSITY OF WISCONSIN- MADISON  
RESEARCH ANIMAL RESOURCES CT  
DIRECTOR, RESEARCH ANIMAL RESOURCES CENTER  
  
1710 UNIVERSITY AVENUE 396 ENZYME INST  
MADISON, WI 53726-4087**

**Customer ID: 616  
Certificate: 35R0001**

**Site: 001  
ALL CAMPUS SITES**

**Inspection  
Type: Routine  
Date: 7 November 2008**

This was an inspection conducted at the College of Agricultural and Life Sciences.  
Note: Annual Report requirements and facility issues were discussed.  
Exit interview conducted with the Associate Director, RARC and other staff members.

Prepared By: Dawn Barksdale DVM Date: 7-NOV-08  
Title: DAWN BARKSDALE, USDA, APHIS, Animal Care  
VETERINARY MEDICAL OFFICER Inspector ID: 1062  
Received By: (b)(6),(b)(7)c Date: 7-NOV-08  
Title:



**INSPECTION REPORT**

**UNIVERSITY OF WISCONSIN-  
MADISON  
RESEARCH ANIMAL RESOURCES CT**

**Customer ID: 616  
Certificate: 35-R-0001**

**Site: 001  
ALL CAMPUS SITES**

**DIRECTOR RESEARCH ANIMAL RESOURCES CENTER  
1710 UNIVERSITY AVENUE 396 ENZYME INST  
MADISON, WI 53726 4087**

**Inspection  
Type: ROUTINE INSPECTION  
Date: DEC-05-2007**

**2.33 ( a )**

**ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.**

(a) Each research facility shall have an attending veterinarian who shall provide adequate veterinary care to its animals in compliance with this section:.....

\*\*A partial review was performed of specific non-human primate records. Animal cy0122 experienced chronic health problems (inappetance and diarrhea) from the time of arrival at the facility in July 2005 until its death in November 2005. Although treatment and observations were well documented, the differential diagnosis of a partial intestinal obstruction/abdominal mass was not pursued in a timely manner, resulting in the death of the animal.

Correction: ensure that appropriate diagnostic and treatment methods are used to provide adequate veterinary care.

Prepared By:

*Dawn Barksdale, DVM*  
DAWN BARKSDALE, D V M , USDA, APHIS, Animal Care

Title

D: 1062

Received By

(b)(6),(b)(7)c

Title

Date:

DEC-05-2007

Date:

DEC-05-2007



**INSPECTION REPORT**

UNIVERSITY OF WISCONSIN-  
MADISON  
RESEARCH ANIMAL RESOURCES CT

Customer ID: 616  
Certificate: 35-R-0001

Site: 001  
ALL CAMPUS SITES

DIRECTOR RESEARCH ANIMAL RESOURCES CENTER  
1710 UNIVERSITY AVENUE 396 ENZYME INST  
MADISON, WI 53726 4087

Inspection  
Type: ROUTINE INSPECTION  
Date: JUN-20-2007

2.31 ( d ) ( 1 ) ( iv ) ( A )

2.31 ( e ) ( 2 )

2.31 ( e ) ( 3 )

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

The regulation states, "(iv) Procedures that may cause more than momentary or slight pain or distress to the animals will:  
(A) Be performed with appropriate sedatives, analgesics or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time;..."

\*\*\*Protocol V660 states animals will be inoculated with a challenge infectious agent and that the disease process will result in some animal morbidity and/or death. A description of affected animals is provided and a scoring system for the determination of euthanasia as an endpoint is outlined for moribund animals. No analgesics will be provided. There is no written justification of the scientific reasons for withholding of any analgesic treatment. Written justification for withholding analgesics must be provided or analgesics must be used.

Correct by: prior to inoculation of any additional animals with infectious agents.

The regulation states, "(e) A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following:...

(2) A rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used..."

\*\*\*Protocol V691 justifies animal numbers by stating, "The numbers of animals are based on our current animal need, however the number listed often exceeds the number of animals we find to place on this protocol. We have a maximum number that are available at any one time for this study and also a minimum that are required for the various studies we perform." This is ambiguous and leaves it very unclear as to the rationale behind the number of animals requested. The principal investigator must provide a clear rationale as to the number of animals needed.

\*\*\*Protocol V660 is also unclear as to the rationale for the number of animals needed. While the principal investigator alludes to USDA or EU animal number requirements for a manufacturer seeking to license a product, it is not clear that licensure is the objective of his proposed activities.

Prepared By: *Dawn Barksdale, DVM*  
DAWN BARKSDALE, D V M , USDA, APHIS, Animal Care

Title: [Redacted] 1062

Received By: [Redacted]

Title: (b)(6),(b)(7)c

Title: [Redacted]

Date:  
JUN-20-2007

Date:  
JUN-20-2007



**INSPECTION REPORT**

JUL 03 2007

Correct by: August 31, 2007

The regulation states, "(e) A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following:...

(3) A complete description of the proposed use of the animals..."

\*\*\*A review of animal records from protocol V660 reveal that a surgical procedure is being conducted (neutering of male cats), but there is no mention nor description of this activity in the approved protocol. The review of nine male cat records indicated that all nine cats had undergone neutering.

Correct by: A full description must be provided and approved by the IACUC prior to any additional surgeries.

\*\*\*The table provided in Protocol V660 describing the approximate time line does not provide a time line. There is a listed vaccine interval, but it is unclear when vaccination is started. Routes of administration of the challenge agent are listed, but time allowed for immunity to develop prior to challenge is unknown. The principal investigator also notes that "experimental design can vary widely between studies" but the experimental design is not clearly stated and what varies widely is unknown.

Correct by: A full description must be provided and approved by the IACUC prior to any additional animal activities.

\*\*\*Protocol V810 involving the use of skunks indicates that laboratory personnel will "score" all animals on an "at least weekly" basis for signs of disease. However, there is no documentation that this is occurring. Protocol V660 also involves a scoring process for each sick animal, but from the records reviewed, scoring was very rarely used. There is no documentation that this tracking procedure is being accomplished as stated in the approved protocol.

Correct by: Immediately

\*\*\*Protocol V691 provides a very broad picture of animal use with very few details provided. The objective is to "better understand the cause or mechanism of spontaneous animal diseases". The description of potential blood collection states, "Blood samples are generally collected at arrival then as required (weekly, monthly) or at most twice weekly. The amount of blood collected is approximately 20 ml for adult cattle, or 10 ml from adult sheep, dogs or cats." Ten ml from a cat twice weekly for an unknown number of weeks is too much and will cause the animal to suffer or die. Humane endpoints are vague, as is treatment for pain. There is mention of the number of animals that will undergo surgery per year, but no explanation of what the surgery involves.

Correct by: A complete description must be provided and approved by the IACUC prior to any animal activities.

2.33 (b)(3)

Prepared By:

*Dawn Barksdale, DVM*

DAWN BARKSDALE, D V M , USDA, APHIS, Animal Care

Title

Received By

Title

(b)(6),(b)(7)c

Date:

JUN-20-2007

Date:

JUN-20-2007



**INSPECTION REPORT**

**2.33 ( b ) ( 5 )**

**ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.**

The regulation states, "(b)(3) Daily observation of all animals to assess their health and well-being; Provided, however, That daily observation of animals may be accomplished by someone other than the attending veterinarian; and Provided, further, That a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian..."

\*\*\*Marked alopecia was noted on the tails of eight skunks. An examination of the animal records showed that this appearance had only been recorded in three of the eight records. Changes in appearance should be noted by care staff as well as research staff and discussed and documented with veterinary staff. Lines of communication are essential to ensure the health and well-being of the animals.

It is the responsibility of the research facility and staff to have a mechanism of direct and frequent communication to ensure problems of animal health and/or behavior are conveyed in a timely manner to the the attending veterinarian. Each research facility is required to establish and maintain programs of adequate veterinary care to maintain the health and well-being of the animals.

Correct by: July 31, 2007

The regulation states, "(b)(5) Adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures."

\*\*\*A review of animal records from Protocol V660 revealed that post-procedural care described in the protocol are not being followed. Monitoring of affected animals is stated as: 3 to 4 times daily after challenge; more often at times that morbidity is greatest; and, when the animals are showing signs of disease or discomfort, the animals are observed at no longer than 8 hour intervals to ensure the animals are euthanized before they die. The records reviewed show that most monitoring has been once (or in a couple of cases, twice) per day when an animal showed signs of disease. Length of time between monitoring points once an animal has begun to show disease signs has lead to unnecessary animal pain and suffering. Monitoring periods should be clearly specified and followed.

Correct by: Immediately

**2.36 ( a )**

**2.36 ( b ) ( 7 )**

**ANNUAL REPORT.**

The regulation states, "(a) The reporting facility shall be that segment of the research facility, or that department, agency, or instrumentality of the United States, that uses or intends to use live animals in research, tests, experiments, or for teaching. Each reporting facility shall submit an annual report to the AC Regional Director for the State where the facility is located on or before December 1 of each calendar year. The report shall be signed and certified by the CEO or Institutional Official, and shall cover the previous Federal fiscal year."

Prepared By:

*Dawn Barksdale, DVM*  
DAWN BARKSDALE, DVM, USDA, APHIS, Animal Care

Date:

JUN-20-2007

Title

Received By

(b)(6),(b)(7)c

Date:

JUN-20-2007

Title

JUL 2 2007



**INSPECTION REPORT**

\*\*\*The 2006 Annual Report must be amended to show the correct numbers of animals. During a review of one principal investigator's animal usage (acquisition records), it was found that he ordered 177 dogs, 41 cats, 6 calves and 2 lambs during the period covered by the 2006 Annual Report. However, this investigator reported only 118 dogs and 41 cats, and no calves or lambs for inclusion on the institution's Annual Report.

Correct by: August 31, 2007

The regulation states, "(7) State the common names and the numbers of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used shall be attached to the annual report..."

\*\*\*All animals that were used and in which pain and/or distress was identified and in which no analgesics were given (as with some animals in protocol V660) must be reflected in Column E of the 2006 Annual Report. An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to the amended report.

Correct by: August 31, 2007

Prepared By:

*Dawn Barksdale, DVM*

DAWN BARKSDALE, D V M , USDA, APHIS, Animal Care

Date:

JUN-20-2007

Received

TI [Redacted] 2  
(b)(6),(b)(7)c  
TI

Date:

JUN-20-2007

JUL 8 2007



United States  
Department of  
Agriculture

February 17, 2011

Marketing and  
Regulatory  
Programs

Alka Chandna

Animal and  
Plant Health  
Inspection  
Service

People for the Ethical Treatment of Animals  
501 Front Street  
Norfolk, Virginia

Legislative and  
Public Affairs

Dear Alka Chandna:

Freedom of  
Information

This is in response to your January 21, 2011 Freedom of Information Act (FOIA) request for copies of documents from November 11, 2009, to present for the University of Utah (87-R-0001) complaint filed by PETA. Your request was received in our office on January 21, 2011, and assigned case number FOIA 11-212.

4700 River Road  
Unit 50  
Riverdale, MD  
20737-1232

Agency employees conducted a thorough search of their files and located 14 pages of responsive records. With this letter we are enclosing the following requested information, correspondence, application for registration, registration certificate, inspection reports, and you're Animal Care Complaint along with the detailed results of this complaint concerning the University of Utah.

However, information has been withheld under FOIA Exemption 6, 5 U.S.C. § 552(b)(6). This exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. In addition, we withheld the same information under FOIA Exemption 7(C), 5 U.S.C. § 552(b)(7)(C). This exemption protects from disclosure records or information collected for law enforcement purposes when its release could reasonably be expected to constitute an unwarranted invasion of personal privacy. Specifically, we have withheld names, addresses and phone numbers.

In addition, the program has informed this office that there are no documents in response to questions three through eight, therefore no records are available.

You may appeal our partial denial of information and our no records determination. If you choose to appeal, your appeal must be in writing and received within 45 days of the date of this letter. Send your appeal to:

Administrator  
Animal and Plant Health Inspection Service  
Ag Box 3401  
Washington, D.C. 20250-3401

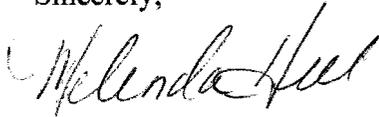
Alka Chandna  
FOIA 11-212

2

If you choose to appeal, please refer to FOIA 11-212 in your appeal letter and add the words "FOIA Appeal" to the front of the envelope. To assist the Administrator in reviewing your appeal, provide specific reasons why you believe modification of the determination is warranted.

Because the cost to process your request is less than \$25.00, the cost has been waived. Should you have questions, please contact Lyndia Taylor of this staff at (301) 734-0597.

Sincerely,



*for* Tonya Woods  
Director  
Freedom of Information & Privacy Act  
Legislative and Public Affairs

Enclosures

Individual  
Lyndia  
AC/IES

171 . 212



Alka Chandna  
<AlkaC@peta.org>  
01/21/2011 01:32 PM

To "foia.officer@aphis.usda.gov" <foia.officer@aphis.usda.gov>  
cc  
bcc

Subject: FOIA Request from PETA pertaining to the University of Utah

January 21, 2011

Dear FOIA Officer,

I hope this e-mail finds you well. This request is made on behalf of People for the Ethical Treatment of Animals (PETA) under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. PETA is a non-profit organization, based in Norfolk, Virginia.

On November 11, 2009, PETA submitted a complaint to the U.S. Department of Agriculture (USDA) requesting the agency to investigate conditions at the University of Utah (87-R-0001) based on problems documented by a PETA undercover investigator who worked inside the university's laboratories.

For the period from November 11, 2009, to the present, I am writing to request copies of the following documents:

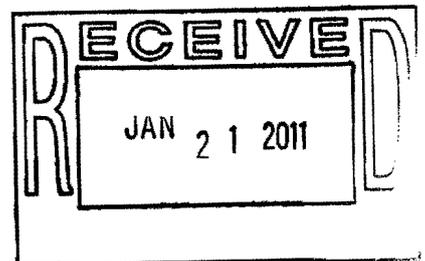
1. Correspondence between the University of Utah and offices of the U.S. Department of Agriculture (USDA);
2. Complete narratives of any inspections and/or investigations conducted by the USDA;
3. Final investigative reports and settlement agreements filed by the USDA;
4. Official warnings issued by the USDA to the University of Utah;
5. Office of General Counsel complaints and stipulations;
6. Photographs taken by USDA inspectors and/or investigators of conditions at the University of Utah;
7. Videos taken by USDA inspectors and/or investigators documenting conditions at the University of Utah; and
8. Correspondence between the USDA and the Office of Laboratory Animal Welfare (OLAW) pertaining to the University of Utah.

As a non-profit public interest organization, PETA asks that all fees be waived. PETA has no commercial interest in the requested information. If the foregoing request for fee waiver is denied, and fees are expected to exceed \$50.00, kindly notify me by telephone to this effect before this disclosure request is processed. If you have any questions pertaining to any aspect of this request, please call me at 410-889-1035 or contact me via e-mail at [alkac@peta.org](mailto:alkac@peta.org).

Thank you for your assistance. I look forward to receiving your reply.

Sincerely,

FEB 18 2011



Alka Chandna



USDA, APHIS, Animal Care



ANIMAL WELFARE COMPLAINT

Complaint No. W10-049	Date Entered 12/30/09	Received By CM
Referred To Watkins	Reply Due	

Facility or Person Complaint Filed Against

Name University of Utah		Customer/License/Registration No. 87-R-0001/CID 12	
Address 75 SOUTH 2000 EAST, SUITE 311			
City Salt Lake City	State UT	Zip 84112	Phone No 8015816840

Complainant

Name Alka Chandna		Organization PETA	
Address 501 Front Street			
City Norfolk	State VA	Zip 23510	Phone No./Email address 757-622-PETA

How was complaint received?  
email

Details of Complaint: Complaint is regarding the treatment of animals by the University of Utah and the IACUC Committee

Results:

Application packet provided? Yes  No

INSPECTOR

DATE

REVIEWED BY

DATE



### ANIMAL WELFARE COMPLAINT

Complaint No. W10-149	Date Entered 12/30/09	Received By CM
Referred To Watkins	Reply Due	

#### Facility or Person Complaint Filed Against

Name University of Utah		Customer/License/Registration No. 87-R-0001/CID 12	
Address 75 SOUTH 2000 EAST, SUITE 311			
City Salt Lake City	State UT	Zip 84112	Phone No 8015816840

#### Complainant

Name Alka Chandna		Organization PETA	
Address 501 Front Street			
City Norfolk	State VA	Zip 23510	Phone No./Email address 757-622-PETA

How was complaint received?  
email

**Details of Complaint:** Complaint is regarding the treatment of animals by the University of Utah and the IACUC Committee

*see attachment*

#### Results:

*see attachment*

Application packet provided? Yes  No

INSPECTOR *Judy Davis*

DATE *2/2/2011*

REVIEWED BY *[Signature]*

DATE *2/10/2011*

**DETAILS/RESULTS/Recommendations:**

1. Alleged failure to maintain a program of adequate veterinary care (9 CFR 2.33 (b)) with regard to:
  - a. Cell-Sorb could be fatal to guinea pigs if eaten—Problem not substantiated and the product is being used per label
  - b. Unclear whether steps were taken to prevent the spread of coccidian between 2 cows—Not substantiated
  - c. No effort made to prevent spread of feline distemper between kittens being treated for distemper and a foster mother with 5 kittens—Not substantiated
  
2. Failed to handle animals in a way that does not cause trauma, behavioral stress, physical harm, or unnecessary discomfort (9 CFR 2.38) with regard to the delivery of 4 female pigs to the CMC:  
Not substantiated as pigs were still under control of the vendor ( who has been determined to not need a license as predominantly agricultural production) and not under control of the registered facility at the time of the incident.
  
3. Failed to ensure that personnel conducting procedures are qualified to perform their duties (9 CFR 2.32 (a)) with regard to:
  - a. Rhesus macaque allegedly circling his cage issue and inadequate monitoring/evaluation of the health of animals—Not substantiated
  - b. Kittens' various deaths —Not substantiated
  
4. Failed to provide safe and adequate housing for pigs and monkeys (9 CFR 3.6 (b)(4), 3.125 (a), 3.1 (a) with regard to:
  - a. Pig allegedly injuring foot when it got stuck in metal grates—Not substantiated
  - b. Escape of 2 monkeys from their cages—Not substantiated
  
5. Failed to provide adequate food and water to a rabbit for 4 days (9 CFR 3.54-3.55):  
IACUC had identified the problem and taken corrective action to prevent future problems before any complaint was received by the facility or USDA
  
6. Failed to provide adequate environment enhancement to promote psychological well-being of nonhuman primates (9 CFR 3.81 (c )(2) with regard to:
  - a. Monkey housed singly with no contact—tactile, visual, auditory, or olfactory—with conspecifics —VALID as to the single housed NHP for whom the Environmental Enhancement Program was not followed
  - b. Pacing of 2 Rhesus macaques during observation by humans—Not substantiated as the pacing that was observed was not considered to be significant given that a stranger was in the room

7. Failed to conform to restrictions on fluid deprivation as a method of training nonhuman primates (9 CFR 2.38 (f)(2)(ii)) :
  - a. Not substantiated
  
8. IACUC Failures:
  - A. Failure to minimize discomfort, distress, and pain to animals (9 CFR 2.31 (d)(1)(i) and 3.128 with regard to a cow with a heart pump:  
Not substantiated under 2.31 (d)(1)(i) but did substantiate IACUC failure under 2.31 (c)(7)
  
  - B. Failed to ensure that Principal Investigators (PIs) "considered alternatives to procedures that may cause more than momentary of slight pain or distress to the animals" (9 CFR 2.31 (d)(1)(ii):  
Not substantiated
  
  - C. Failed to ensure that the "animals' living conditions will be appropriate for their species... and contribute to their health and comfort: (9 CFR 2.31 (d)(1)(vi)) :  
Not substantiated as enrichment is not required under the AWA for pigs, rabbits, and dogs
  
  - D. Failed to ensure that proposed protocols were adequately complete—including caveats for how particular (and not unlikely) scenarios would be handled. As a result of this failure, deficient protocols were approved and more animals than would be required to obtain valid results were used (9 CFR 2.31 (e)(3):  
Not substantiated

The week long inspection from 1/24-29/2010 was conducted by myself and a VMO from the Eastern Region and involved approximately 70 hours work by each VMO.

Subsequent inspections occurred on 4/8/2010, 6/14/2010, and 7/14/2010. The 7/14/2010 inspection was conducted by myself and another Western Region VMO.

No corrective actions are recommended at this time due to the efforts of the facility to immediately and proactively correct problems.

*Judy W. Davis, DVM, MBA*  
Judy W. Davis, DVM, MBA

USDA, APHIS, AC, VMO

2-2-2011



United States  
Department of  
Agriculture

Animal and Plant  
Health Inspection  
Service

Animal Care  
Western Region

2150 Centre Ave.  
Building B  
Mail Stop # 3W11  
Ft. Collins, CO 80526  
Phone: 970-494-7478  
Fax: 970/494-7461

RE: REGISTRATION UPDATE  
Certificate Number: 87-R-0001  
Renewal Date: 07/16/2010

May 13, 2010  
Customer ID Number: 12

(b)(6)

University Of Utah  
Office Of Comparative Medicine  
75 South 2000 East (b)(6)  
Salt Lake City, UT 84112

Dear Registrant:

This is a reminder that your Animal Welfare Registration is due for update ON or BEFORE the renewal date shown above. This is the only notice you will receive.

The Code of Federal Regulation (9 CFR), Subpart B, Sections 2.25 and 2.30 states that all registrants must update the information on their registration every 3 years. Please complete the enclosed Application for Registration (Aphis Form 7011) and sites listing, and return them to this office before your anniversary date. After receiving the completed forms, we will mail you a copy of the completed forms and a new registration certificate.

Please note that you must have an approved, complete and up-to-date program of veterinary care form (PVC) on file at your place of business. You can obtain blank PVC forms -- or any other forms you may need -- directly from this office or your USDA inspector. The AWA also requires that you report to us any changes in your name, address, location, management, control or ownership of your business via Certified Mail within 10 days after the change has occurred.

The AWA also requires that you report to us any changes in your name, address, location, management, control or ownership of your business via Certified Mail within 10 days after the change has occurred.

We appreciate your efforts in complying with the Animal Welfare Act. Contact this office at (970) 494-7478 if you have any questions regarding this letter or the Animal Welfare Act.

Sincerely,

Robert M. Gibbens, D V M  
Regional Director – Animal Care  
Western Region

cc: Judy W. Davis, D.V.M.

Enclosures



Safeguarding American Agriculture  
APHIS is an agency of USDA's Marketing and Regulatory Programs  
An Equal Opportunity Provider and Employer

11-212/000005



United States  
Department of  
Agriculture

Animal and Plant  
Health Inspection  
Service

Animal Care  
Western Region

2150 Centre Ave.  
Building B  
Mail Stop # 3W11  
Ft. Collins, CO 80526  
Phone: 970-494-7478  
Fax: 970/494-7461

RE: ACKNOWLEDGEMENT OF UPDATE

Certificate Number: 87-R-0001

Anniversary Date: 07/16/2013

July 20, 2010

Customer ID Number: 12

(b)(6)

University Of Utah  
Office Of Comparative Medicine  
75 South 2000 East (b)(6)  
Salt Lake City, UT 84112

Dear Registrant:

Thank you for submitting your USDA Registration renewal form. Enclosed for your files is a copy of your APHIS Form 7011 (Application for Registration) and Registration Certificate showing that your registration under the Animal Welfare Act has been renewed for another 3 years.

This Application for Registration is to be filed every 3 years on or before your renewal date. You will receive a renewal notice approximately 60 days before your renewal date. You may discontinue your registration under the Animal Welfare Act any time you desire by submitting a written request for cancellation of your registration to this office.

You are reminded that your records must be kept current. They are subject to review by the Animal Care personnel when they visit your premises. Record-keeping forms may be ordered from this office at no charge.

The law requires you to notify this office, in writing, of any changes in the name, address, location, management, control or ownership of your business within 10 days after such a change has been made.

We appreciate your efforts in complying with the Animal Welfare Act. Contact this office at (970) 494-7478 if you have any questions regarding this letter or the Animal Welfare Act.

Sincerely,

Robert M. Gibbens, D V M  
Regional Director – Animal Care  
Western Region

cc: Judy W. Davis, D.V.M.

Enclosures



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

An Equal Opportunity Provider and Employer

11-212/000006

9

Every research facility, exhibitor, carrier, and intermediate handler not required to be licensed under Section 3 of the Animal Welfare Act, shall register with the USDA (7 USC 2136). This application provides information for such registration.

OMB No. 0579-0036  
FORM APPROVED

U.S. DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE  
**APPLICATION FOR REGISTRATION**  
(TYPE OR PRINT)

**USDA USE ONLY**

Applicant should send completed form to this address.  
USDA APHIS ANIMAL CARE  
Western Region  
2150 Centre Ave.  
Building B, Mailstop 3W11  
Fort Collins, CO 80526-8117  
(970) 494-7478

**REGISTRATION UPDATE**

**CERTIFICATE NO./CUST NO:**  
87-R-0001  
12

**RENEWAL DATE**  
16-Jul-2010

**1. REGISTRANT (Name and permanent mailing address, including Zip Code)**

UNIVERSITY OF UTAH  
Office Of Comparative Medicine  
75 South 2000 East, Suite 311  
Salt Lake City, UT 84112  
  
COUNTY: SALT LAKE TELEPHONE (801) - 581 - 6840

**2. LOCATION(S) OF BUSINESS, EXHIBITION STIE(s), OR RESEARCH FACILITIES (Use additional sheets if necessary)**

**NOT A FOIA DELETION**  
2030 East 50 North University of Utah  
500 Pothill Drive Office of Comparative Medicine  
Salt Lake City, UT 84108 75 S 2000 E, Suite 311  
County: SALT LAKE SLC, UT 84112  
County: Salt Lake  
801-581-6840  
(b)(6) 801-581-6840

**3. (A) PREVIOUS USDA REGISTRATION NUMBER (IF ANY)**

N/A

**4. (B) ACTIVE USDA CERTIFICATE NUMBER(S) IN WHICH YOU HAVE AN INTEREST:**

N/A

**5. ARE YOU USING FEDERAL FUNDS TO CARRY OUT**

RESEARCH, TESTS, OR EXPERIMENTS

Yes  No

**6. TYPE OF REGISTRATION:**

Class E - Exhibitor  Class H - Intermediate Handler  
 Class R - Research Facility  Class T - Carrier

**7. FEDERAL FUND TYPES:**

Award  Contract  Grant  Loan

**8. TYPE OF ORGANIZATION:**

Partnership  Corporation  Individual  
 Other (Specify) University

list

**9. IF INDIVIDUAL IDENTIFY EACH OWNER, IF PARTNERSHIP IDENTIFY EACH PARTNER OR OFFICER, IF CORPORATION, IDENTIFY PRINCIPAL OFFICERS FOR RESEARCH FACILITIES INCLUDE THE INSTITUTIONAL OFFICIAL (Use separate sheet if needed)**

A. NAME	B. TITLE	C. ADDRESS (full address, including ZIP Code)
(b)(6)		201 S. Presidents Circle, (b)(6) SLC, UT 84112 Office of Comparative Medicine 75 S 2000 E, #311, SLC, UT 84112-8930

**CERTIFICATION**

I hereby register as a Research Facility, Exhibitor, Carrier, or Intermediate Handler under the Animal Welfare Act, 7 U.S.C. 2131 et seq. and I certify that the information provided herein is true and correct to the best of my knowledge and belief, and that I am familiar with all the regulations and standards contained in 9 CFR, Subpart A, parts 1, 2 and 3. I certify that all listed persons are

11. NAME AND TITLE (Type or Print) (b)(6)  
12. DATE SIGNED 06/28/2010



**United States  
Department of  
Agriculture**

**Marketing and  
Regulatory  
Programs**

**Animal and  
Plant Health  
Inspection  
Service**

**Animal Care**

EXPIRATION DATE: JULY 16, 2013

This is to certify that

UNIVERSITY OF UTAH

is a registered

under the

CLASS R RESEARCH FACILITY

## **Animal Welfare Act**

(7 U.S.C. 2131 et seq.)

Certificate No.

87-R-0001

Customer No.

12

A handwritten signature in cursive script that reads "Charles A. Gipsom". The signature is written in black ink and is positioned above a horizontal line.

Deputy Administrator

11-212/000008



## Inspection Report

---

UNIVERSITY OF UTAH

Customer ID: **12**

Certificate: **87-R-0001**

Site: 001

UNIVERSITY OF UTAH

OFFICE OF COMPARATIVE MEDICINE

Type: ROUTINE INSPECTION

SALT LAKE CITY, UT 84112

Date: Jun-14-2010

---

No noncompliances identified during this focused inspection.

Exit interview was conducted with the Directors of the Office of Comparative Medicine and the IACUC.

---

**Prepared By:**

JUDY W DAVIS, D.V.M. USDA, APHIS, Animal Care

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 5022

Jun-28-2010

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

**Title:**

Jun-28-2010



## Inspection Report

UNIVERSITY OF UTAH

Customer ID: 12

Certificate: 87-R-0001

Site: 001

UNIVERSITY OF UTAH

OFFICE OF COMPARATIVE MEDICINE

Type: ROUTINE INSPECTION

SALT LAKE CITY, UT 84112

Date: Apr-08-2010

**2.33 (b) (2) REPEAT**

**ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.**

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:  
(2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care;

The facility is not always using appropriate methods to treat with antibiotics or to monitor the animals during anesthesia, even though they have established programs of veterinary care. Examples include:

--An eleven day old kitten began a veterinarian prescribed twice daily treatment with Amoxicillin on 4/6/10. On 4/7/10, the Amoxicillin was given at 09:00 am and approximately 15:00. The next dose was given on 4/8/10 at approximately 07:00 am. This is an interval of 16 hours between doses. Twice daily antibiotics should be given at intervals of approximately 12 hours. Antibiotics are not as effective when given at inappropriate intervals and this may endanger the animals.

--A primate was anesthetized for 20 minutes while the veterinarian sutured the primate's finger. No evidence of monitoring during the procedure could be furnished. The IACUC approved monitoring procedures require: "Write in data at least every 15 minutes during surgery." The facility needs to follow the IACUC approved procedures for monitoring anesthesia to ensure the safety of the animals.

The facility needs to ensure that appropriate methods to prevent, control, diagnose and treat diseases and injuries are consistently applied, including the use of correct drug dosing intervals and appropriate monitoring during anesthesia.

Previous correction date assigned on 3-24-2010 was "from this point forward".

Exit interview was conducted with the Directors of the Office of Comparative Medicine and the IACUC.

**Prepared By:**

JUDY W DAVIS, D.V.M. USDA, APHIS, Animal Care

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 5022

Jun-10-2010

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

**Title:**

Jun-11-2010



## Inspection Report

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UNIVERSITY OF UTAH

Customer ID: 12

Certificate: 87-R-0001

Site: 001

UNIVERSITY OF UTAH

OFFICE OF COMPARATIVE MEDICINE

Type: ROUTINE INSPECTION

SALT LAKE CITY, UT 84112

Date: Aug-24-2009

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No noncompliances identified during this inspection.

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**Prepared By:**

JUDY W DAVIS, D.V.M. USDA, APHIS, Animal Care

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 5022

Aug-25-2009

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

**Title:**

Aug-25-2009



## Inspection Report

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UNIVERSITY OF UTAH

Customer ID: 12

Certificate: 87-R-0001

Site: 001

UNIVERSITY OF UTAH

OFFICE OF COMPARATIVE MEDICINE

Type: ROUTINE INSPECTION

SALT LAKE CITY, UT 84112

Date: Aug-29-2008

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No noncompliances identified during this inspection.

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**Prepared By:**

JUDY W DAVIS, D.V.M. USDA, APHIS, Animal Care

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 5022

Aug-29-2008

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

**Title:**

Aug-29-2008



## Inspection Report

UNIVERSITY OF UTAH

Customer ID: 12

Certificate: 87-R-0001

Site: 003

UNIVERSITY OF UTAH

OFFICE OF COMPARATIVE MEDICINE  
75 SOUTH 2000 EAST, SUITE 311  
SALT LAKE CITY, UT 84112

Type: ROUTINE INSPECTION

Date: Jul-14-2010

### 2.33 (b) (2)

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:

(2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care;

--The facility is not always using appropriate methods to prepare for aseptic surgery. A craniotomy on a primate was performed on 7/12/10 in a surgery area that had been used for another animal procedure several days earlier and not prepared afterwards as an aseptic surgery area. The IACUC approved protocol for this procedure called for an aseptically prepared surgery area. Maintenance of an aseptic surgery room is important during major operative procedures to prevent infection. The research facility shall maintain programs of adequate veterinary care that include the use of appropriate methods to prevent and control diseases such as aseptically prepared surgery areas for major operative procedures.

Correct immediately.

--The facility has outdated drugs ready for use, not labeled as expired, and commingled with non-expired drugs. The expired drugs included Tequin (expiration 10/2005), Trepicamide Solution (Expiration 11/2007), Gonak (one with expiration 9/2008 and one with expiration 4/2007). Expired drugs may be ineffective, toxic, or contaminated with bacteria, and could injure the animals. The facility must establish and maintain programs of adequate veterinary care that ensure drugs used on the animals are safe and effective.

Correct immediately.

### 3.75 (e)

#### HOUSING FACILITIES, GENERAL.

Open food and bedding supplies must be kept in leakproof containers with tightly fitting lids to prevent spoilage and contamination.

--Two bags of open cereal used for marmoset treats are stored in a file drawer and not in sealed

#### Prepared By:

JUDY W DAVIS, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5022

Aug-16-2010

#### Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Aug-16-2010



## Inspection Report

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containers to prevent contamination. Open food supplies must be kept in leakproof containers with tightly fitting lids to prevent spoilage and contamination.

Correct by 7/15/10.

Inspection conducted with Attending Veterinarian and IACUC Director. Exit interview was conducted with IACUC Director. Tracy Thompson, USDA, APHIS, AC, VMO was also present for the inspection and exit interview.

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**Prepared By:**

JUDY W DAVIS, D.V.M. USDA, APHIS, Animal Care

**Title:** VETERINARY MEDICAL OFFICER Inspector 5022

**Date:**

Aug-16-2010

**Received By:**

(b)(6), (b)(7)(c)

**Date:**

Aug-16-2010

**Title:**