All redactions on this page are pursuant to (b)(6) & (b)(7)(c).



APR 2 8 2010

CERTIFIED MAIL RETURN RECEIPT

United States Department of Agriculture

Animal and Plant Health Inspection Service

Marketing & Regulatory Programe Business Services

4700 River Road Riverdale, MD 20737 3901 Rainbow Blvd. 1040 Wescoe Pavillion – MS2014 Kansas City, KS 66160

University of Kansas Medical Center

Dear Sir(s):

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

Our investigation shows that you have violated the United States Code of Federal Regulations as described on the enclosed Stipulation. APHIS laws and regulations provide for administrative and criminal penalties to enforce these regulatory requirements, including civil penalties of \$125,000 for the violations documented in our investigation.

The Secretary of Agriculture may, after providing notice and opportunity for a hearing, impose civil penalties or other sanctions. You may, however, waive your right to a hearing and settle this matter by paying \$62,500 by June 07, 2010 and signing the enclosed Stipulation.

Please pay the \$62,500 penalty by certified check or money order made payable to the Treasurer of the United States. Write the Case Number (KS09015-AC) on your check or money order and mail it with the signed Stipulation to:

USDA, APHIS, (General) (KS09015-AC) P. O. Box 979043 St. Louis, MO 63197-9000

If we do not receive your signed stipulation agreement and payment or notice that you wish to exercise your right to a hearing by June 07, 2010, this matter will be forwarded to the Department's Office of the General Counsel (OGC) for litigation. Please know that the penalty offered in this Stipulation represents a fraction of the civil penalty APHIS may seek should we refer this matter to OGC. You may contact our office at telephone number (301) 734-8684 if you have any questions.



Bernadette Juarez Deputy Director Investigative and Enforcement Services

Enclosure



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

An Equal Opportunity Provider and Employer

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Investigative and Enforcement Services

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

RESPONDENT:

University of Kansas Medical Center

3901 Rainbow Blvd. 1040 Wescoe Pavillion – MS2014 Kansas City, KS 66160 CASE NUMBER KS09015-AC DUE ON OR BEFORE June 7, 2010

Settlement Agreement

CONTACT

June 7, 2010 Ms (301) 734

DATE	CITATION	DESCRIPTION	
	a standarda da ana ana ang kata si panan ang kata ka pananana		
		See Attached Pages (Page 1 of 7)	
PENALTY	l s 62.500.		

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

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

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

Signature of Respondent:

Date:

PAYMENT RECORD - FOR IES USE ONLY

Payment Type	Date	Amount	Signature of IES Representative
]		

T04 – Settlement Agreement Revised 11/15/05 All redactions on this page are pursuant to (b)(2)High & (b)(7)(F).

FOIA 10-549		3 of 241
DATE	<u>CITATION</u> 9 CFR	DESCRIPTION
10-MAR-2009	2.31(d)(2)(iv)(B)	Institutional Animal Care and Use Committee (IACUC). For protocol 2007:1688 failed to include planning and consultation with the attending veterinarian on procedures that may cause more than momentary or slight pain and/or distress to animals.
	2.33(b)(2)	Attending Veterinarian and Adequate Veterinary Care. Failed to establish and maintain adequate programs of veterinary care that included the use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care. APHIS observed the following: 1) An investigator cart in procedure room that contained expired drugs (8 vials) of ketamine (expiration date 6/08) and one bottle of Nembutal Sodium Solution/Pentobarbital 50 mg/ml (exp. 9/1/08) also, butterfly catheters were stored in a drawer with an aerosol can of "Clippercide" spray. 2) In procedure room macaques, a bottle of children's chewable vitamins were stored immediately adjacent to cleaning solutions. 3) In room an oral pill dispenser was observed being stored in a container with grooming supplies including nail clippers and a comb. A large white rabbit was observed with a persistent, abnormal head tilt to the right. 4) In room (Fenbendazole) was being stored on a soap dispenser adjacent to cleaning chemicals. 5) A macaque was observed with red to brown colored crusty discharge around the resin on his surgically placed acrylic head cap. 6) Twenty six nonhuman primates were observed to have hair loss and/or excessive scratching.
	2.33(b)(3)	Attending Veterinarian and Adequate Veterinary Care. Failed to establish and maintain adequate programs of veterinary care that included the daily observation of all animals to assess their health and well-being. APHIS observed several animals that had medical problems that had not been documented by animal caretakers nor communicated to the veterinary staff including a white rabbit (in room with a persistent, abnormal head tilt to the right; twenty six non human primates with varying amounts of hair loss and excessive scratching, including one animal that was thin.
	3.56(c)	Sanitation. Housekeeping. Failed to keep premises (building and grounds) clean and in good repair in order to protect animals from injury and to facilitate prescribed husbandry practices. The refrigerator room was observed with a thick layer of brown to tan dusty material on top. There was also a large quantity of spilled bedding present. In room the tan containing waste material.

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FOIA 10-549		4 of 241
<u>DATE</u>	<u>CITATION</u> 9 CFR	DESCRIPTION
10-MAR-2009	3.75(a)	Housing Facilities, general. Structure. Construction. Failed to provide housing facilities for nonhuman primates that are designed and constructed to be structurally sound, kept in good repair, and to protect the animals from injury. APHIS observed cages (18 squirrel monkeys) in room had a two inch by four inch opening at the front of the enclosures risking injury to the animal. The following non human primate rooms had drain covers that had been removed for cleaning and not replaced: room (2 squirrel monkeys); room (4 macaques); room (17 squirrel monkeys); room (11 squirrel monkeys in ront, 11 in back); and room (18 squirrel monkeys).
	3.75(c)(1)	Housing Facilities, general. Surfaces. General Requirements. Failed to provide surfaces in housing facilities that are constructed in a manner and made of materials that allow them to be readily cleaned and sanitized, or removed or replaced when worn or soiled. In room (housing 10 macaques), the drywall behind the hose was observed bowing out and had a roughened surface with peeling paint. This area is no longer impervious to moisture and can no longer be effectively cleaned and sanitized.
	3.75(f)	Housing Facilities, general. Drainage and waste disposal. Failed to provide for regular and frequent collection, removal, and disposal of animal and food wastes, bedding, dead animals, debris, garbage, water, and any other fluids and wastes, in a manner that minimizes contamination and disease risk. APHIS observed several rooms housing nonhuman primates in which the trash cans were not covered. Rooms with uncovered or partially uncovered trash cans included: (4 macaques) (10 macaques), (6 macaques), and two trash cans on the dirty side of a cage wash used to clean nonhuman primate enclosures. Standing water was observed in the following room (housing 16 squirrel monkeys), room (housing 18 squirrel monkeys), room (housing 10 macaques); and room (housing 3 macaques) standing water was observed on the bottom shelf of the television cart.
	3.81(c)(2)	Environment Enhancement to Promote Psychological Well- Being. Special considerations. Failed to provide special attention regarding enhancement of environment, based on the needs of the individual species and in accordance with the instructions of the attending veterinarian. Twenty-six nonhuman primates had variable degrees of hair loss ranging from partial to full loss of hair on the tail to patchy hair loss on the body. An additional seven nonhuman primates were observed by APHIS to be actively picking or stripping hair from their bodies or exhibiting stereotypic behaviors such as flipping or swaying.

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FOIA 10-549		5 of 241
<u>DATE</u>	<u>CITATION</u> 9 CFR	DESCRIPTION
10-MAR-2009	3.81(e)(2)	Environment Enhancement to Promote Psychological Well- Being. Failed to appropriately exempt animals from the environmental enrichment plan. The committee approved an exemption to environment enhancement for squirrel monkeys on protocol 2007:1688; but the IACUC has not approved this exemption on an individual basis. Several squirrel monkeys had variable degrees of hair loss, which can be a sign of psychological distress.
	3.82(a)	Feeding. Failed to provide a diet of food that is clean, wholesome, palatable to the animals, of sufficient nutritive value for non human primates that is appropriate for the species, size, age, condition of the animal, and for the conditions in which the nonhuman primate is maintained. APHIS officials observed three containers of baby food used as treats for non human primates in the investigator lab in room G010. These containers of food were expired.
19-APR-2009	2.31(d)(5)	Institutional Animal Care and Use Committee (IACUC). Failed to conduct continuing review of activities at appropriate intervals as determined by the IACUC. Protocol 2007-1703; Protocol 2008-1735; and Protocol 2007-1680.
	2.31(e)(4)	Institutional Animal Care and Use Committee (IACUC). Failed to have a sufficiently detailed description of the procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable. Protocol 2007-1703, a guinea pig protocol, includes conflicting information concerning the dose and/or route of administration of anesthetic and analgesic drugs.
	2.33(b)(2)	Attending Veterinarian and Adequate Veterinary Care. Failed to establish and maintain adequate programs of veterinary care that included the use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care. APHIS officials observed the following: 1) two squirrel monkeys (ID#668 and ID#702) wearing beaded metal collars that were rusty; 2) Macaque (ID#99R1027) was prescribed acetaminophen, but was given ibuprofen instead; 3) Medical records for a male macaque (ID#99R1027) stated that the chamber had not been cleaned in 3 weeks; 4) Medical records for macaque (ID#0A0) do not document that any veterinarian performed any evaluations, physical examinations, diagnosis, or developed any treatment plan from 10/07/08 through 10/16/08; and 5) In protocol 2008-1735 failed to weigh monkeys on a regular basis to check for normal weight gain as stated in the protocol.

All redactions on this page are pursuant to (b)(2)High & (b)(7)(F).

FOIA 10-549		6 of 241
DATE	<u>CITATION</u> 9 CFR	DESCRIPTION
14-APR-2009	2.33(b)(3)	Attending Veterinarian and Adequate Veterinary Care. Failed to establish and maintain adequate programs of veterinary care that included the daily observation of all animals to assess their health and well-being. Checklists reviewed at this inspection showed that completion of daily observations (health check) were not documented on four occasions; all of which were on the weekend; Room (April 11 and April 12); Room April 4 and April 5).
	3.75(c)(1)	Housing Facilities, General. Surfaces. Failed to have facilities made of materials that allow them to be readily cleaned and sanitized as required. In room housing 15 squirrel monkeys, there were areas of chipping and peeling paint on the wall in at least two areas exposing the bare cinder blocks which cannot be effectively cleaned and sanitized.
	3.75(c)(1)(i)	Housing Facilities, General. Surfaces. Failed to have fixtures constructed of materials that allow them to be readily cleaned and sanitized as required and free of excessive rust. A metal hook on one of the straps used to secure the perches in a squirrel monkey enclosure had rusted to the point that it could no longer be effectively cleaned and sanitized.
	3.75(e)	Housing Facilities, General. Storage. Failed to store supplies of food and bedding in a manner that protects the supplies from spoilage, contamination, and vermin infestation. A pallet of bedding in the second floor storage room, used to store primate feed and other animal supplies was stored against the wall, preventing the required cleaning (SOP HUSB 1 Food, Water, and Bedding Management).
	3.81(b)	Environment Enhancement to Promote Psychological Well- Being. Failed to develop and follow a program of monitoring and maintenance to ensure that all enrichment items for nonhuman primates are kept in good repair and can be effectively cleaned and sanitized. At least 4 metal circular discs, which are supposed to be reflective and act as mirrors to provide enrichment for the nonhuman primates were scratched to the point that the surface was no longer reflective. At least three "chew toys" observed to be chewed to the point that the surface was extremely grooved and pitted to the point that they could no longer be effectively cleaned and disinfected.

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DATE	<u>CITATION</u> 9 CFR	DESCRIPTION
1 4-APR-2909	3.81(c)(2)	Environment Enhancement to Promote Psychological Well- Being. Special Considerations. Failed to provide special attention regarding enhancement of their environment, based on the needs of the individual species and in accordance with the instructions of the attending veterinarian. Several nonhuman primates had variable degrees of hair loss ranging from partial to full loss of hair on the tail to patchy hair loss on the body; several were observed by APHIS to be actively picking and showing signs of possible psychological distress.
	3.125(c)	Facilities, General. Storage. Failed to develop and follow a program that ensures that all supplies of food and bedding are stored in facilities which adequately protect such supplies from deterioration, molding, or contamination by vermin. The ground floor storage room used to store gerbil bedding was nearly filled with pallets of bedding leaving only a small open area at the entrance of the room, preventing the required cleaning (SOP HUSB 1 Food, Water, and Bedding Management).
30-JUN-2009	2.31(d)(5)	Institutional Animal Care and Use Committee (IACUC). Failed to conduct continuing review of activities at appropriate intervals as determined by the IACUC. Investigators for Protocol 2008-1735 are not conducting animal activities as delineated in the IACUC approved protocol. MRI anesthetic procedures states that nonhuman primates will be tranquilized with ketamine. The laboratory written procedure for MRI utilized by the laboratory staff states that the animals are given a full dose of ketamine followed by a "Dormitor" for transport, which is then followed by a ½ dose of ketamine every 30 minutes thereafter.
	2.31(e)(2)	Institutional Animal Care and Use Committee (IACUC). Failed to ensure that all protocols include an appropriate rationale for the number of animals to be use. Protocol 2009-1796 did not contain a scientific justification for the appropriateness of the number of animals being used.
	2.31(e)(3)	Institutional Animal Care and Use Committee (IACUC). Failed to provide a complete description of the proposed use of the animals to facilitate the evaluation of the protocols by the IACUC. Protocol 2007-1680 did not contain a complete description of the proposed use of the animals.

"Rimadyl".

records showed that medications were not administered as prescribed by the veterinarian: Macaque #AV82- four missed doses of metronidazole; macaques #5A9, 5A3, 702, 3A1- missed one dose metronidazole; macaque #99R1837 missed one dose cephalexin; and squirrel monkey #11F - missed one dose

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All redactions on this page are pursuant to (b)(6) & (b)(7)(c).

FOIA 10-549

UNITED STATES DEPARTMENT OF AGRICULTURE

ANIMAL AND PLANT HEALTH INSPECTION SERVICE INVESTIGATIVE AND ENFORCEMENT SERVICES

REPORT OF INVESTIGATION

Case Number: KS09015-AC

(Contact Information) Center

Subject(s): University of Kansas Medical

Investigator:

(Contact Information)

USDA APHIS IES

2150 Centre Avenue Bldg B 3W10 Fort Collins Colorado 80526 970-494 620-202

USDA APHIS IES 2150 Centre Avenue Bldg B 3W10 Fort Collins Colorado 80526 970-494 573-352

usda aphis IES 2150 Centre Avenue Bldg B 3W10 Fort Collins Colorado 80526 970-494 573-233

Date of Report: 02/18/10

 \mathbf{N} Substantiated allegation(s)

No violation(s)

Fact finding

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Reviewer(s)

Date: 02/18/10

SYNOPSIS

USDA APHIS Animal Care conducted five inspections at the University of Kansas Medical Center (UKMC) Kansas City, Kansas on 8/27/08, 12/18/08, 3/10/09, 4/14/09, and 6/30/09. The USDA APHIS AC inspections document UKMC's failure to submit an Annual Report and their repeated failure to provide veterinary care; cleaning and facility maintenance; Institutional Animal Care Use Committee (IACUC) oversight, feeding, sanitation, drainage and waste disposal, primary enclosures, numerous violations that affect the psychological well being of nonhuman Primates, and an inadequate number of properly trained employees.

FOIA 10-549 Case Number: KS09015-AC

BACKGROUND

Subject(s) Information

UKMC is registered with USDA as a Research Facility with registration number 48-R-0003 (<u>Exhibit</u> <u>1</u>). UKMC's 2009 Annual Report to USDA lists as their Institutional Official (<u>Exhibit 2</u>). UKMC is a Division of the University of Kansas Center for Research (<u>Exhibit 3</u>). The University of Kansas Center for Research is registered with the Kansas Secretary of State as a Not for Profit Corporation, corporation number 0031468 (<u>Exhibit 4</u>).

Subject(s) Previous History

Prior Enforcement Actions

A review of the IES Tracking System shows no previous history for UKMC.

Prior Adjudications N/A

NARRATIVE

Basis for Investigation

On 4/14/09, Dr. Robert Gibbens, Director Western Region USDA APHIS AC, requested USDA APHIS IES initiate an investigation of UKMC for: repeated failure to provide adequate veterinary care, repeated failure to properly clean and maintain facilities, numerous IACUC oversight violations, numerous violations that affect the psychological well-being of nonhuman Primates, and an inadequate number of properly trained employees (Exhibit 5).

Investigative Findings

August 27, 2008

On 8/27/08 Dr. Katheryn Ziegerer (USDA APHIS AC Veterinary Medical Officer (VMO)) and Dr. Jamilon Niemann (USDA APHIS AC VMO) conducted an inspection at UKMC (Exhibit 6) and documented the following non-compliant items:

UKMC – IACUC failed to provide a specific plan and schedule for correction dates on deficiencies identified in the IACUC Fall 2007 and Spring 2008 Facility Reviews (Exhibit 7-8).

Adequate Veterinary Care - UKMC failed to provide adequate veterinary care for nonhuman primates.

Feeding - UKMC failed to provide wholesome food for guinea pigs.

Housekeeping - UKMC failed to provide adequate housekeeping of rabbit housing facilities; Inspection Photographs (<u>Exhibit 9</u>).

Structure, Construction - UKMC failed to maintain the surfaces in nonhuman primate housing facilities; Inspection Photographs (<u>Exhibit 10</u>).

Surfaces, General Requirements - UKMC failed to maintain the surfaces of nonhuman primate housing facilities so that they were impervious to moisture. Inspection Photographs (Exhibit 11).

Drainage and Waste Disposal - UKMC failed to provide adequate drainage and waste disposal for necropsy samples and medications. Inspection Photographs (Exhibit 12).

Feeding - UKMC failed to provide wholesome for nonhuman primates as the enrichment foods being fed were expired.

December 18, 2008

On 12/18/08 Dr. Ziegerer conducted an inspection of UKMC (<u>Exhibit 13</u>). Dr. Ziegerer documented the UKMC Annual Report dated 11/12/08 (<u>Exhibit 14 (Section 9.E</u>) failed to include two exemptions to the AWA which had been approved by UKMC IACUC Committee (<u>Exhibit 15 (Section 11.1 and 11.8.5</u>).

March 10, 2009

On 3/10/09 Dr. Ziegerer and Dr. Tanya Tims (USDA APHIS AC Supervisory Veterinary Medical Officer (SVMO) conducted an inspection of UKMC (Exhibit 16) that documented the following non-compliant items:

UKMC IACUC – IACUC Committee Minutes dated 10/16/07 and 11/20/07(<u>Exhibit 17 (Section 5.0)</u> and <u>Exhibit 18 (Section 6.0)</u>) approved Protocol 2007-1688, the PI failed to include planning and consultation with the attending veterinarian on procedures that cause more than momentary or slight pain or distress to animals.

UKMC IACUC – IACUC Committee Minutes dated 10/16/07 and 11/20/07(Exhibit 17 (Section 5.0) and Exhibit 18 (Section 6.0)) approved Protocol 2007-1688 (Exhibit 19 (Section 6.1)) that failed to justify by scientific reason the use of an animal in more than one major operative procedure.

UKMC IACUC – IACUC Committee Minutes dated 10/16/07 and 11/20/07(Exhibit 17 (Section 5.0) and Exhibit 18 (Section 6.0)) approved Protocol 2007-1688 (Exhibit 19 (Section 6.1)) that failed to justify for scientific reasons procedures that may cause more than momentary or slight pain or distress to the animal.

UKMC IACUC failed to conduct appropriate reviews of animals activities to ensure the Protocol 2007-1688 (Exhibit 19 (Section 9.0)) manipulative environment enhancement exemption has not had a negative impact on the welfare of the animals; and failed to conduct appropriate reviews of animals activities to ensure the 10-30 minute monitoring of non-human primates that had transferred from the surgical table to the incubator Protocol 2007-1688 (Exhibit 19 (Section 6.3.5)) and Laboratory Animal Record #1911 (Exhibit 20). Principal Investigator Dr. responded (Exhibit 21) to this item.

UKMC IACUC failed to make recommendations to the Institutional Official regarding any aspect of the animal facility. UKMC IACUC Meeting Minutes 3/24/08, 4/14/08, 5/20/08, 6/17/08, 7/15/08 and 8/19/08 (Exhibits 22-27) indicate increased research activity has exceeded the existing infrastructure;

UKMC IACUC failed to ensure the principal investigators for Protocol 2007-1688 (Exhibit 19 (Section 5.3)) and Protocol 2007-1686 (Exhibit 28 (Section 5.3)) considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animal. Dr. Ziegerer by affidavit (Exhibit 29) and Protocol 2007-1686 Principal Investigator Dr. by response (Exhibit 30) provide additional response to this item.

UKMC IACUC failed to ensure Protocol 2007-1688 (Exhibit 19 (Section 5.3, 6.3.4, 6.3.5)) was designed to assure that discomfort and pain to animals are limited in sufficient detail for the IACUC to

FOIA 10-549 determine whether or not the procedures are adequate to protect the welfare of the animals. Dr. Ziegerer provides additional response to this item (Exhibit 29).

UKMC IACUC failed to ensure a complete description of the proposed use of the animals and is not specific on how many major survival surgeries each animal will undergo prior to euthanasia Protocol 2007-1688 (Exhibit 19 (Section 6.1)); Adequate Veterinary Care – documents numerous non-compliant veterinary care issues Inspection Photographs (Exhibit 31). Dr. Ziegerer provides additional response to this item (Exhibit 29).

Adequate Veterinary Care - UKMC failed to establish and maintain adequate programs of daily observation of animal Husbandry Room Checklists (Exhibit 32).

Annual Report – UKMC did not report any nonhuman primates on the Annual Report (<u>Exhibit 33</u>) upon which experiments, research, surgery, or tests were conducted involving pain or distress to the animals 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. UKMC Amended Annual Report 4/3/09 (<u>Exhibit 34</u>) and Protocol 2007-1688 (<u>Exhibit 19 (Section 5.3</u>)) documents inaccurate pain classifications.

Annual Report – UKMC did not report at least thirty two nonhuman primates on the annual report as being bred, conditioned or held (<u>Exhibit 33</u>). UKMC Amended Annual Report 4/3/09 (<u>Exhibit 34</u>) lists three dogs, five guinea pigs, twenty hamsters and twenty three nonhuman primates as being bred, conditioned or held. Dr. Ziegerer provides additional response to this item (<u>Exhibit 29</u>).

UKMC 2008 Annual Report Amendment (<u>Exhibit 35</u>) documents UKMC IACUC approved an exemption to housing standards to allow one nonhuman primate to be housed in an enclosure that did not meet minimum height requirements was in effect for approximately one month. IACUC Meeting Minutes March-May 2008 documents IACUC exemption approval more than one month (<u>Exhibit 23-25</u>).

Facilities, General – Structural Strength, Inspection Photographs (<u>Exhibit 36</u>) document UKMC failed to ensure housing facilities were kept in good repair.

Sanitation – Housekeeping, Inspection Photographs (<u>Exhibit 37</u>) document UKMC failed to keep facilities free of clutter, spilled feed, unused items, and open trash containers.

Sanitation - Pest Control; UKMC failed to have an adequate program for the control of insects.

Employees - UKMC failed to have appropriately trained employees in regards to proper sanitation practices.

Housing Facilities – Structure- Construction, Inspection Photographs (<u>Exhibit 38</u>); UKMC failed to maintain housing facilities for nonhuman primates which were structurally and protected the animals from injury.

Housing Facilities – Surfaces, Inspection Photographs (<u>Exhibit 39</u>); UKMC failed to maintain the surfaces of housing facilities in good repair and could be readily cleaned and sanitized.

FOIA 10-549 Housing Facilities – Storage, Inspection Photographs (Exhibit 40); UKMC failed to properly store cleaning and food supplies.

Housing Facilities – Drainage/Waste Disposal, Inspection Photographs (<u>Exhibit 41</u>); UKMC failed to have adequate drainage and waste disposal systems to rapidly remove standing water.

Housing Facilities – Surfaces – Cleaning, Inspection Photographs (<u>Exhibit 42</u>); UKMC failed to adequately clean and sanitize housing facility surfaces and primary enclosures of nonhuman primates.

Housing Facilities – Surfaces, Inspection Photographs (<u>Exhibit 43</u>). UKMC failed to maintain housing facility surfaces which were free of rust and could be adequately cleaned and sanitized.

Primary Enclosures, Inspection Photographs (<u>Exhibit 44</u>); UKMC failed to provide the minimum space requirements for nonhuman primates. Dr. Ziegerer provides additional response to this item (<u>Exhibit 29</u>).

Environment Enhancement – Social Grouping, SOP PROG 8 (<u>Exhibit 45</u>); UKMC failed to address the group and social housing requirements for nonhuman primates which live in social groups in the wild.

Environment Enhancement – Environmental Enrichment, Inspection Photographs (<u>Exhibit 46</u>); UKMC failed to provide environmental enrichment items and toys which were in good repair.

Environment Enhancement – SOP PROG 8 (Exhibit 45) and Protocol 2007-1688 (Exhibit 19 (Section 9.0)). UKMC failed to provide adequate environment enhancement items for nonhuman primates.

Environment Enhancement – Special Considerations, SOP PROG 8 (<u>Exhibit 45</u>); UKMC failed to house nonhuman primates in a manner which allowed the animals to be visible to each other.

Environment Enhancement – Exemptions, Protocol 2007-1688 (Exhibit 19 (Section 9.0)) and IACUC Committee Meeting Minutes (Exhibit 47 and 23.); UKMC failed to approve environment enhancement exemptions on an individual animal basis and failed to review the exemptions to ensure animals were not negatively affected.

Environment Enhancement – Special Considerations; UKMC failed to develop and follow an enhancement plan for nonhuman primates which were exhibiting signs of psychological distress.

Feeding, Inspection Photographs (<u>Exhibit 48</u>); UKMC failed to provide wholesome food to nonhuman primates as treats being fed were past their expiration dates.

Sanitization, Inspection Photographs (<u>Exhibit 49</u>); UKMC failed to adequately sanitize primary enclosures as the cagewash was incapable of reaching 180 degrees F.

Housekeeping, Inspection Photographs (<u>Exhibit 50</u>); UKMC failed to provide adequate housekeeping in nonhuman primate housing facilities.

Pest Control, Inspection Photographs (<u>Exhibit 51</u>); UKMC failed to have an effective program for the control of rodents.

17 of 241 Employees; UKMC failed to have a sufficient number of adequately trained employees to provide for the proper care and handling of nonhuman primates.

Facilities - Storage, Inspection Photographs (Exhibit 52); UKMC failed to properly store supplies of hav.

Sanitation, Inspection Photographs (Exhibit 53); UKMC failed to adequately clean and sanitize gerbil enclosures as the cagewash was incapable of reaching 180 degrees F.

Pest Control, Inspection Photographs (Exhibit 54); UKMC failed to have an effective program for the control of pests in the gerbil storage ro

Housekeeping Inspection Photographs (Exhibit 55); UKMC failed to provide adequate housekeeping in the housing facilities of gerbils.

Employees; UKMC failed to have a sufficient number of adequately trained employees to provide the professionally acceptable level of husbandry practices.

April 14, 2009

On 4/14/09 Dr. Ziegerer and Dr. Ruth Bakker (USDA APHIS AC VMO) conducted an inspection (Exhibit 56) at UKMC that documented the following non-compliant items:

UKMC IACUC - Protocol 2008-1735 (Exhibit 57 (Section 5.3)) and Protocol 2008-1703 (Exhibit 58 (Section 5.3)) and Protocol 2008-1680 (Exhibit 59 (Section 5.3)) do not include terms that relate to the procedures that may cause more than momentary or slight pain or distress to the animals. Protocol 2008-1735 Principal Investigator response (Exhibit 60), Protocol 2008-1703 Principal response (Exhibit 61). Protocol 2008-1680 Principal Investigator Investigator response (Exhibit 62).

UKMC IACUC failed to ensure personnel conducting procedures on regulated species must be appropriately gualified and trained. Protocol 2008-1703 (Exhibit 58 (Section 6.9)), Protocol 2008-1 1703 Principal Investigator (and Research Assistant Training Records (Exhibit 63) and response (Exhibit 61).

UKMC IACU onduct appropriate reviews of animal activities to ensure the principle investigators are conducting animal activities as delineated in Protocol 2007-1703 (Exhibit 58 (Section 5.3) (Section 6.3.3)(Section 6.9)), Protocol 2008-1735 (Exhibit 57 (Section 6.6)(Section 6.1)), Protocol 2008-1680 (Exhibit 59 (Section 6.1) (Section 6.4.2)(Section 6.5)), Lab Animal Records B5-AL11 and B4-2A0 and B2-4A4 and A5-3A5 and A2-5A9 and C1-57Z and C2-5A# (Exhibit 64), Protocol 2008-1703 Principal Investigator response (Exhibit 61), Protocol 2008-1735 Principal Investigator response (Exhibit 60), Protocol 2008-1680 Principal Investigator response (Exhibit 62).

18 of 241 UKMC IACUC failed to ensure that all protocols include an appropriate rationale for the number of animals to be used. Protocol 2007-1680 (Exhibit 59 (Section 5.3) (Section 6.1)) and Protocol 2008-1680 Principal Investigator response (Exhibit 62).

UKMC IACUC approved protocols that did not contain a complete description of the proposed use of the animals. Protocol 2008-1703 (Exhibit 58) and Protocol 2008-1703 Principal Investigator response (Exhibit 61). Protocol 2007-1680 (Exhibit 59 (Section 6.1)) and Protocol 2008-1680 response (Exhibit 62), Protocol 2008-1735 (Exhibit 57 (Section Principal Investigator 6.1) and Protocol 2008-1735 Principal Investigator response (Exhibit 60).

UKMC IACUC - approved protocols that did not include a sufficiently detailed description of the procedures designed to assure that discomfort and pain to animals will be limited to animals to that which is unavoidable. Protocol 2007-1703 (Exhibit 58 (Section 6.3.5)) and Protocol 2008-1703 Principal Investigator response (Exhibit 61).

UKMC IACUC failed to ensure that all protocols to conduct an activity involving animals contain an appropriate description of the method of euthanasia to be used. Protocol 2008-1735 (Exhibit 57 (Section 6.9)(Section 12.0)(Section 6.1)) and Protocol 2008-1735 Principal Investigator response (Exhibit 60).

Personnel Qualification - UKMC failed to ensure all individuals involved in animal care, treatment and use must be qualified to perform their duties and appropriately trained. SOP 5 Personnel Training (Section 3.5) t 65) and Protocol 2008-1735 Principal Investigator Training Record (Exhibit oo).

Adequate Veterinary Care; UKMC failed to maintain a program of adequate veterinary care that included the use of appropriate methods to prevent, control, diagnose and treat animals. Inspection Photographs (Exhibit 67), Laboratory Animal Record for #99R1027 dated 10/14/08 and 12/7/08 (Exhibit 68), Protocol 2008-1735 Principal Investigator response (Exhibit 60). Laboratory Animal Records #0A0 dated 10/7/08 and 10/15-17/08 (Exhibit 69), Research Assistant emails on #0A0 dated 10/8/08 and 10/16/08 (Exhibit 70), Investigator Records #0A0 dated 7/21/08 and 10/15/08 document a 22% weight loss (Exhibit 71), Laboratory Animal Records #3A0 dated 10/7/08, 10/9/08, 10/10/08 (Exhibit 72) and Principal Investigator and Research Assistant emails dated 10/9/08 and 10/10/08 (Exhibit 73) and #0A0 Medical Records (Exhibit 74) document the animal appears to have met the criteria for euthanasia days prior to being euthanized. Protocol 2007-1703 (Exhibit 58 (Section 6.3.6 and Section 6.5) and Protocol 2008-1703 Principal Investigator response (Exhibit 61) document failure to provide adequate veterinary care. Protocol 2008-1735 (Exhibit 57 (Section 6.1)) and Protocol 2008-1735 Principal Investigator response (Exhibit 60) document failure to provide and maintain adequate programs of veterinary care. Protocol 2008-1735 (Exhibit 57 (Section 6.7)), Primate Master Record #99R1027, #674, #622, #702, #668, #695 (Exhibits75-80) and Protocol 2008-1735 Principal Investigator response (Exhibit 60) document the lack of a system of health records of sufficiently comprehensive to demonstrate the delivery of an adequate program of veterinary care.

Inspection Report (Exhibit 56) and Inspection Photographs (Exhibit 81) document UKMC failure of daily observation of all animals to assess their health and well being.

19 of 241 Miscellaneous - Handling, Protocol 2008-1735 (Exhibit 57 (Section 6.4.2)), Primate Master Record #99R1027 (Exhibit 75) and Protocol 2008-1735 Principal Investigator response (Exhibit 60) document UKMC IACUC failed to ensure adequate handling in respect to approved protocols.

Housing – Surfaces – Inspection Report (Exhibit 56) and Inspection Photographs (Exhibit 82) document UKMC failure of maintenance to ensure all surfaces are free of excessive rust.

Housing – Surfaces, Inspection Report (Exhibit 56) and Inspection Photographs (Exhibit 83) document UKMC failure of maintenance to ensure all surfaces to be readily cleaned and sanitized.

Housing - Storage - Inspection Report (Exhibit 56), Inspection Photographs (Exhibit 84) and SOP HUSB 1 Food, Water and Bedding Management (Exhibit 85 (Section 4.2.7)) document UKMC failure to store bedding in a manner that allows adequate cleaning.

Indoor Housing - Lighting, Inspection Report (Exhibit 56) and Inspection Photographs (Exhibit 86) document failure to provide adequate lighting to permit routine inspection.

Primary Enclosures - Inspection Report (Exhibit 56), Protocol 2007-1688 (Exhibit 19 (Section 10)) documents failure to provide sufficient volume of space.

Environment Enhancement - Inspection Report (Exhibit 56), Inspection Photographs (Exhibit 87) and SOP Prog 8 Promotion of Psychological Well Being of Non-human Primates (Exhibit 88- page 3 (Section 1(c)) document UKMC failed to develop and follow a program of monitoring and maintenance to ensure all enrichment items are kept in good repair.

Environment Enhancement - Inspection Report (Exhibit 56), Inspection Photographs (Exhibit 89), Inspection Video (Exhibit 90) and SOP Prog 8 Promotion of Psychological Well Being of Non-human Primates (Exhibit 88) documents UKMC failure to develop and follow a plan to ensure nonhuman primates showing signs of psychological distress receive considerations with regard to enhancement;

Facilities - Storage, Inspection Report (Exhibit 56), Inspection Photograph (Exhibit 91) and SOP HUSB 1 Food, Water and Bedding Management (Exhibit 85 (Section 4.2.7)) document UKMC failure to store bedding in a manner that allows adequate cleaning.

June 30, 2009

On 6/30/09 Dr. Ziegerer and Dr. Niemann conducted an inspection (Exhibit 92) at UKMC that documented the following non-compliant items:

UKMC IACUC - Protocol 2007-1619 (Exhibit 93 (Section 19)) and Protocol 2006-1581 (Exhibit 94 (Section 19)) did not include terms that relate to the procedures that may cause more than momentary or slight pain or distress to the animals. Protocol 2007-1619 Principal Investigator Dr. (Exhibit 95) and Protocol Dr. 2006-1581 (Exhibit 96) respond to adequate alternatives or alternative methods to more than momentary or slight pain or distress to animals.

UKMC IACUC - Protocol 2007-1619 (Exhibit 93), Protocol 2006-1581 (Exhibit 94), Protocol 2009-1796 (Exhibit 97), Protocol 2007-1680 (Exhibit 59) and Dr. Ziegerer affidavit (Exhibit 29) document four protocols were reviewed and approved by a single member of the IACUC.

FOIA 10-549 UKMC IACUC – Protocol 2008-1735 (Exhibit 57 (Section 6.1 and 6.6)) and MRI Scan Procedures (Exhibit 98) document Principal Investigators are not conducting animal activities as delegated in the approved protocol;

UKMC IACUC – protocol 2009-1796 (Exhibit 97 (Section 6.1 and Section 6.3)) and Dr. Ziegerer affidavit (Exhibit 29) document failure to contain scientific justification for the appropriateness of the number of animals being used.

UKMC IACUC – Protocol 2007-1680 (Exhibit 59 (Section 4.0) and Section 5.0 and Section 6.1)) document failure of the complete description of proposed use of animals;

Adequate Veterinary Care, Animal Treatment Records #AV82, #5A9, #5A3, #702, #3A1 and #99R1837 (Exhibits 99-104) document failure to provide adequate veterinary care; Adequate Veterinary Care, Laboratory Animal Record #11F (Exhibit 105) and Dr. Ziegerer (Exhibit 29) document failure to provide adequate veterinary care;

Indoor Housing Facilities – Lighting, Inspection Report (<u>Exhibit 92</u>) documents failure to provide adequate lighting to permit routine inspection.

On 7/29/09 Dr. Tanya Tims (USDA APHIS AC VMO) confirms assisting Dr. Ziegerer with a UKMC Inspection on 3/10/09 (Exhibit 106).

On 8/5/09 Dr. Jamilon Niemann (USDA APHIS AC VMO) confirms assisting Dr. Ziegerer with UKMC Inspections on 8/27/09 and 6/10/09 (Exhibit 107).

On 8/8/09 Investigator , met with Thomas Field, Interim Associate Vice Chancellor for Compliance of UKMC and received documents that had been requested by IES, to be used as evidence to support the alleged violations (Exhibits 2, 4, 7, 8, 14, 15, 17, 18, 19, 21, 22, 23, 24, 25, 26, 27, 28, 30, 32, 33, 34, 35, 45, 47, 57, 58, 59, 66, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 85, 88, 93, 94 and 105).

On 10/21/2009, Investigator Walker contacted Thomas Field, UKMC, by email with questionnaires to be completed by (IO), Dr. , Dr. , Dr. , Dr. Dr. Dr. , Dr. PI, PI, PI and Warren Nothnick IACUC Chair. On 12/11/09, Investigator received an email from Thomas Field containing the completed questionnaires (Exhibits 21, 30, 60, 61, 62, 95, 96, 109, 110 and 111).

E-mails (3) between (USDA APHIS IES) and Thomas Field UKMC responses to USDA Inspections of UKMC (Exhibit 112).

On 11/30/09 Dr. Ruth Bakker (USDA APHIS AC VMO) confirms assisting Dr. Ziegerer with UKMC Inspection on 4/14/09 (Exhibit 108).

On 12/11/09 Dr. (UKMC Attending Veterinarian) responded to questions posed by USDA APHIS IES relating to USDA APHIS AC Inspections conducted at UKMC on 8/27/08, 3/10/09, 4/14/09 and 6/30/09 (Exhibit 109).

On 12/11/09 Dr. (UKMC Vice Chancellor of Administration and UKMC Institutional Official) responded to questions posed by USDA APHIS IES relating to USDA APHIS AC Inspections conducted at UKMC on 8/27/08, 12/18/08, 3/10/09, 4/14/09 and 6/30/09 (Exhibit 110).

All redactions on this page are pursuant to (b)(6) & (b)(7)(c).

FOIA 10-549 On 12/11/09 Dr. (UKMC IACUC) responded to questions posed by USDA APHIS IES relating to USDA APHIS AC Inspections conducted at UKMC on 8/27/08, 3/10/09, 4/14/09 and 6/30/09 (Exhibit 111).

E-mail between Rodney Walker (USDA APHIS IES) and relating to responses to USDA Inspections of UKMC (Exhibit

<u>113</u>).

On 12-14-09, Investigator received a package from Thomas Field, which contained the attachments that were referenced in Harold Phillips questionnaire (Exhibit114)

Interview Log prepared by IES, explaining why UKMC declined to sign affidavits (Exhibit 115).

These findings substantiate the following alleged violation(s):

9 C.F.R. § 2.31(c)(3) - IACUC functions.

On 8/27/09, UKMC failed to provide a specific plan and schedule for correction dates on deficiencies identified in the IACUC Fall 2007 and Spring 2008 Facility Review. This regulation requires, if program or facility deficiencies are noted the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency.

9 C.F.R. § 2.31(c)(5) – IACUC functions.

On 3/10/09, UKMC failed to make recommendations to the Institutional Official regarding increased research activity had exceeded the existing infrastructure creating a need for additional support for the Laboratory Animal Resources. This regulation requires the IACUC make recommendations to the Institutional Official regarding any aspect of the research facilities animal program, facilities or personnel training.

9 C.F.R § 2.31(d)(1)(ii) – IACUC review of activities involving animals.

On 3/10/09, 4/14/09, and 6/30/09, UKMC failed to include alternative terms that relate to the procedures that may cause more than momentary or slight pain or distress to the animals. This regulation requires the principal investigator consider alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and has a written narrative description of the methods and sources.

9 C.F.R § 2.31(d)(1)(iv)(A) – IACUC review of activities involving animals.

On 3/10/09, UKMC failed to justify for scientific reasons procedures that may cause more than momentary or slight pain or distress to the animal. This regulation requires procedures that may cause more than momentary or slight pain or distress to animals be performed with

appropriate sedatives, analgesics or anesthetics unless withholding such agents is justified for scientific reasons.

9 C.F.R. § 2.31(d)(1)(iv)(B) – IACUC review of activities involving animals.

On 3/10/09, UKMC failed to include planning and consultation with the attending veterinarian on procedures that cause more than momentary or slight pain or distress to animals. This regulation requires procedures that cause more than momentary or slight pain or distress to animals involve in their planning, consultation with the attending veterinarian.

9 C.F.R § 2.31(d)(1)(viii) – IACUC review of activities involving animals.

On 4/14/09, UKMC failed to ensure personnel conducting procedures on regulated species were appropriately qualified and trained. This regulation requires personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained on those procedures.

9 C.F.R. § 2.31(d)(1)(x) – IACUC review of activities involving animals.

On 3/10/09, UKMC failed to justify by scientific reason the use of at least one non-human primate that underwent three major survival surgeries. This regulation requires no animal will be used in more than one major operative procedure unless justified.

9 C.F.R § 2.31(d)(2) – IACUC review of activities involving animals.

On 6/10/09, UKMC allowed four protocols to be reviewed and approved by a single committee member without being available to all members for review and approval from each of the committee members. This regulation requires protocols shall be available to all IACUC members for review.

9 C.F.R § 2.31(d)(5) – IACUC review of activities involving animals.

On 3/10/09, 4/14/09 and 6/30/09, UKMC failed to conduct appropriate reviews of animal activities to ensure compliance with compliance with AWA Regulations and Standards. This regulation requires the IACUC shall conduct continuing reviews of activities covered by the AWA at appropriate intervals.

9 C.F.R. § 2.31(e)(2) – IACUC.

On 4/14/09 and 6/30/09, UKMC failed to ensure that all protocols include scientific justification for the appropriateness of the number of animals being used for research purposes. This regulation requires a scientific rationale for involving animals, and justification for numbers of animals being used.

9 C.F.R. § 2.31(e)(3) – IACUC.

On 3/10/09, 4/14/09, and 6/30/09, UKMC failed to ensure all proposals to conduct animal activities contain a complete description of proposed use of animals. This regulation requires a complete description of the proposed use of animals.

9 C.F.R. § 2.31(e)(4) – IACUC.

On 3/10/09 and 4/14/09, UKMC approved protocols that did not include a sufficiently detailed description of the procedures designed to assure that discomfort and pain to animals will be limited to animals to that which is unavoidable. This regulation requires protocols

include a sufficiently detailed description of the procedures designed to assure that discomfort and pain to animals will be limited to animals to that which is unavoidable.

9 C.F.R. § 2.31(e)(5) – IACUC.

On 4/14/09, UKMC failed to ensure that all protocols to conduct an activity involving animals contain an appropriate description of the method of euthanasia is to be used. This regulation requires a description of any euthanasia method being used.

9 C.F.R. § 2.32(a) – Personnel qualifications.

On 4/14/09, UKMC failed to ensure all individuals involved in animal care, treatment and use must be qualified to perform their duties and appropriately trained. This regulation requires all personnel involved in the animal care, treatment, and use is qualified to perform their duties. This responsibility shall be fulfilled in part through the provision training and instruction.

9 C.F.R. § 2.33(b)(2) – Adequate Veterinary Care.

On 8/27/08, 3/10/09, 4/14/09, and 6/30/09, UKMC failed to maintain a program of adequate veterinary care that includes the use of appropriate methods to prevent, control, diagnose and treat animals. This regulation requires the use of appropriate methods to prevent, control, diagnose and treat animals.

9 C.F.R. § 2.33(b)(3) – Adequate Veterinary Care.

On 3/10/09 and 4/14/09, UKMC failed to conduct daily observation of all animals to assess their health and well being. This regulation requires daily observations of all animals to assess their health and well being.

9 C.F.R. § 2.33(b)(5) - Adequate Veterinary Care.

On 6/30/09, UKMC failed to provide adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures. This regulation requires adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures.

9 C.F.R. § 2.36(b)(3) – Annual Report.

On 12/18/08, UKMC's Annual Report failed to include two exemptions to the AWA which had been approved by UKMC IACUC Committee. This regulation requires a summary of all exceptions to the standards and regulations be attached to the facility's annual report.

9 C.F.R. § 2.36(b)(7) – Annual Report.

On 3/10/09, UKMC did not report any nonhuman primates on the Annual Report upon which experiments, research, surgery, or tests were conducted involving pain or distress to the animals 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. This regulation requires reporting any nonhuman primates on the Annual Report upon which experiments, research, surgery, or tests were conducted involving pain or distress to the animals for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures to the animals 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

9 C.F.R. § 2.36(b)(8) – Annual Report.

On 3/10/09, UKMC did not report at least thirty two nonhuman primates on the annual report as being bred, conditioned, or held. This regulation requires reporting the common names and the numbers of animals being bred, conditioned or held for use in teaching, testing, experiments, research or surgery but not yet used for such purposes.

9 C.F.R. § 2.38(b)(1)(iv) – Miscellaneous – Access and inspection of records and property.

On 3/10/09, UKMC failed upon multiple direct requests to accompany the USDA Inspectors into a non-human primate room during the inspection. This regulation requires each research facility to allow access and inspection of facilities as APHIS Officials consider necessary to enforce the provisions of the Act.

9 C.F.R. § 2.38(f)(2)(ii) – Miscellaneous – Handling.

On 4/14/09, UKMC failed to ensure all approved protocols involving the short term withholding of food and water from animals include a description of monitoring procedures. This regulation requires an IACUC approved activity that involves deprivation of food or water include a description of monitored procedures.

9 C.F.R. § 2.38(k)(1) – Miscellaneous – Compliance with standards ad prohibitions.

On 3/10/09, UKMC failed to justify an approved exemption to housing standards to allow one nonhuman primate to be housed in an enclosure that did not meet minimum height requirements. This regulation requires each research facility shall comply with all respects with the regulations set forth in 9 CFR 2 (c) and standards set forth in 9 CFR 3.

9 C.F.R. § 3.25 (a) – Facilities General.

On 3/10/09, UKMC failed to maintain housing facilities for guinea pigs which were structurally sound and in good repair. This standard requires each housing facilities for guinea pigs to develop a program of monitoring and maintenance to ensure that all facilities are structurally sound, and maintained in good repair.

9 C.F.R. § 3.29 (a) - Feeding.

On 8/27/08, UKMC failed to provide wholesome food for guinea pigs. This standard requires each housing facility for guinea pigs provide feed that was free from contamination, wholesome, palatable and sufficient quantity and nutritive value to meet the daily requirements.

9 C.F.R. § 3.56 (c) - Sanitation - Housekeeping.

On 8/27/08 and 3/10/09, UKMC failed to keep rooms housing rabbits free from peeling paint, mold and waste materials. This standard requires each housing facility for rabbits develop and follow a program of monitoring and maintenance to ensure that all premises are kept clean and good repair.

9 C.F.R. § 3.56 (d) – Sanitation – Pest Control.

⁴⁹ On 3/10/09, UKMC failed to keep an animal receiving room free from insects on the floor. This standard requires each housing facility housing rabbits must have an effective program for the control of insects, ectoparasites, and avian and mammalian pests.

9 C.F.R. § 3.57 Employees.

On 3/30/09, UKMC failed to keep food/water receptacles clean from tan scaly material. This standard requires each housing facility housing rabbits must ensure that a sufficient number of appropriately trained employees are utilized in order to maintain the prescribed level of husbandry practices.

9 C.F.R. § 3.75 (a) – Housing Facilities, General.

On 8/27/08 and 3/10/09, UKMC failed to maintain rooms housing squirrel monkeys in good repair. This standard requires each housing facility housing nonhuman primates to design, construct and maintain facilities that housed nonhuman primates so that they are structurally sound for the species of nonhuman primates housed in them.

9 C.F.R. § 3.75 (c)(1) Housing Facilities, General – Surfaces.

On 8/27/08 and 3/10/09, UKMC failed to maintain rooms housing squirrel monkeys free from chipping and peeling paint and surfaces which were impervious to moisture. This standard requires housing facilities for nonhuman primates be constructed in a manner that allows them to be readily cleaned and sanitized.

9 C.F.R. § 3.75(c)(1)(i) Housing Facilities, General – Surfaces.

On 3/10/09 and 4/14/09, UKMC failed to maintain rooms housing squirrel monkeys which could be effectively cleaned and sanitized. This standard requires housing facilities housing nonhuman primates to have all surfaces that come in contact with the nonhuman primates free of excessive rust that prevents required cleaning and sanitation.

9 C.F.R. § 3.75 (c)(3) Housing Facilities, General – Surfaces – Cleaning.

On 3/10/09, UKMC failed to maintain rooms housing macaques free of excessive accumulation of fecal material, food residue and drip marks of black to gray material. This standard requires each housing facility housing nonhuman primates to ensure that all hard surfaces which nonhuman primates come into contact with are spot cleaned daily and sanitized.

9 C.F.R. § 3.75 (e) Housing Facilities, General – Storage.

On 3/10/09 4/14/09, UKMC failed to have cleaning supplies, medicines, food and opened food treats stored in an orderly manner. This standard requires each housing facility housing nonhuman primates develop and follow a program of monitoring and maintenance to ensure that supplies of food and bedding are stored in a manner that protects the supplies from spoilage, contamination, and vermin infestation.

9 C.F.R. § 3.75 (f) Housing Facilities, General – Drainage and waste disposal.

On 8/27/08 and 3/10/09 UKMC failed maintain housing facilities of nonhuman primates which were free of standing water on the floors and uncovered trash cans were present. This standard requires housing facilities housing nonhuman primates to provide regular and frequent removal of water and other fluid waste in order to minimize contamination/disease

risk, and drainage is constructed in a manner that minimizes contamination and disease hazard and trash containers must be leak proof and have tightly fitted lids.

9 C.F.R. § 3.76 (c) Indoor Housing Facilities – Lighting.

On 4/14/09 and 6/30/09, UKMC failed to have sufficient lighting to perform inspection and to observe the animals. This standard requires each facility housing nonhuman primates to provide adequate lighting to permit routine inspection and must be uniformly diffused throughout animal facilities to provide sufficient illumination to aid in maintaining good housekeeping practices.

9 C.F.R. § 3.80 (b) (2) (i) Primary Enclosures.

On 3/10/09, UKMC failed to provide adequate space for one adult squirrel monkey which was being housed in an infant incubator. This standard requires each facility housing nonhuman primates to provide minimum space to each nonhuman primate, whether housed individually or with other primates. This minimum space will be determined by the typical weight of the animal of its species.

9 C.F.R. § 3.80 (c) Primary Enclosures.

On 4/14/09, UKMC IACUC approved temporary use of a human infant incubator which did not provide sufficient space for squirrel monkeys while in post-operative recovery. This standard requires the licensee to ensure that all approved innovative enclosures for nonhuman primates provide the nonhuman primates with a sufficient volume of space.

9 C.F.R. § 3.81 Environment enhancement to promote psychological well-being.

On 3/10/09, UKMC failed to develop, document, and follow an appropriate plan for environment enhancement to promote the psychological well-being of nonhuman primates. This standard requires an appropriate plan for environment enhancement adequate to promote the psychological well being of nonhuman primates.

9 C.F.R. § 3.81(a) Environment enhancement to promote psychological well-being – Social grouping.

On 3/10/09, UKMC failed to ensure an environment enhancement plan with specific provisions to address the social needs of nonhuman primates of species known to exist in social groups in nature. This standard requires the environment enhancement plan must include specific provisions to address the social needs of nonhuman primates of species known to exist in social groups in nature.

9 C.F.R. § 3.81 (b) Environment enhancement to promote psychological well-being.

On 3/10/09 and 4/14/09, UKMC failed to provide enrichment reflectors and toys which were in good repair. This standard requires the licensee to develop and follow a program of monitoring and maintenance to ensure that all enrichment items for nonhuman primates are kept in good repair.

9 C.F.R. § 3.81 (c)(2) Environment enhancement to promote psychological well-being.

On 3/10/09 and 4/14/09, UKMC failed to keep twenty eight nonhuman primates from exhibiting abnormal stereotypic behaviors that could be associated with psychological distress. This standard requires the licensee to develop and follow a plan to ensure that those

nonhuman primates that show signs of being in psychological distress thorough behavior or appearance receive special considerations with regard to enhancement of their environment.

9 C.F.R. § 3.81 (c)(4) Environment enhancement to promote psychological well-being. On 3/10/09, UKMC housed seven macaques with no visual contact with other nonhuman primates. This standard requires the licensee ensure a facility plan for environment enhancement is followed and documented for individually housed nonhuman primates.

9 C.F.R. § **3.81 (e)(2) Environment enhancement to promote psychological well-being**. On 3/10/09, UKMC IACUC failed to develop and follow a plan to ensure nonhuman primates showing signs of psychological distress were evaluated. This standard requires the IACUC must review at appropriate intervals the exemption of an individual nonhuman primate from participation of environment enhancement.

9 C.F.R. § 3.82 (a) Feeding,

On 8/27/08 and 3/10/09, UKMC failed to provide wholesome food for nonhuman primates as food items were past their expiration or best by dates. This standard requires the licensee to develop a program to ensure that all feed is free from contamination, wholesome, palatable, and of sufficient quantity and nutritive value.

9 C.F.R. § 3.84 (b)(3) Cleaning, Sanitization, Housekeeping, and Pest Control

On 3/10/09, UKMC failed to sanitize nonhuman primate enclosures with required temperatures of at least 180 degrees on at least three dates. This standard requires all hard surfaces of primary enclosures housing nonhuman primates be cleaned and sanitized by live steam or washing with at least 180 degree hot water.

9 C.F.R. § 3.84 (c) Cleaning, Sanitization, Housekeeping, and Pest Control

On 3/10/09, UKMC failed to have areas housing nonhuman primates free of towels, clothing and other materials which inhibited adequate husbandry practices. This standard requires the licensee to ensure all premises are kept clean and in good repair in order to protect the nonhuman primates from injury and facilitate the husbandry practices.

9 C.F.R. § 3.84 (d) Cleaning, Sanitization, Housekeeping, and Pest Control

On 3/10/09, UKMC had a box style rodent trap that was located on the shelf of the television cart rather than on the floor. This standard requires the licensee to have an effective program for control of insects and external parasites.

9 C.F.R. § 3.85 Employees

On 3/10/09, UKMC failed to ensure employees were adequately trained in husbandry practices and the care and handling of nonhuman primates. This standard requires the employees who provide husbandry, care, or handle nonhuman primates must be trained and supervised by an individual who has the knowledge, background, and experience in proper husbandry and care of nonhuman primates.

9 C.F.R. § 3.125 (c) Facilities, General – Storage

On 3/10/09 and 4/14/09, UKMC failed to have hay and clean bedding stored in a manner which protected the bedding from deterioration and/or contamination. This standard requires the licensee to ensure all supplies of food and bedding are stored in facilities which adequately protect such supplies against deterioration, molding, or contamination by vermin.

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On 3/10/09, UKMC failed to have the cagewash capable of reaching temperatures to ensure adequate sanitation of surfaces. This standard requires the licensee to ensure that all cages are effectively cleaned and sanitized.

9 C.F.R. § 3.131 (c) Sanitation – Housekeeping

On 3/10/09, UKMC had accumulations of discarded construction materials in a room used to store bedding for gerbils which inhibited adequate cleaning and sanitation. This standard requires the licensee to keep all premises clean and in good repair in order to protect the animals from injury and to facilitate the prescribed husbandry practices.

9 C.F.R. § 3.131 (d) Sanitation – Pest Control,

On 3/10/09, UKMC failed have an effective program for the control rodents. This standard requires the licensee to provide an effective program for the control of insects, ectoparasites, and avian and mammalian pests.

9 C.F.R. § 3.132 Employees

On 3/10/09, UKMC failed to have a sufficient number of adequately trained employees to maintain the professionally acceptable level of husbandry practices. This standard requires a sufficient number of adequately trained employees shall be utilized to maintain the professionally acceptable level of husbandry practices.

These findings indicate that the evidence does not support a violation of the following section(s): N/A

MITIGATING AND/OR AGGRAVATING FACTORS

N/A

ADDITIONAL INFORMATION

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APHIS form 7023 UKMC Annual Report of Research Facility dated 11/30/09 (Exhibit 116).

All redactions on this page are pursuant to (b)(6) & (b)(7)(c).

FOIA 10-549 Case Number: KS09015-AC 30 of 241 Date: 02/18/10

<u>WITNESS LIST</u> Provide First, MI and Last Name with Complete Address				
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All redactions on this page	are pursuant to (b)(6) & (b)(7)(c).	
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	Department of Anatomy and	University of Kansas Medical
	Cell Biology	Center
		3901 Rainbow Blvd.
		Kansas City, Ks 66160
		(913) 588-
David M. Pinson	Laboratory	University of Kansas Medical
	Animal Resources Professor	Center 3901 Rainbow Blvd.
		Kansas City, Ks 66160
		(913) 588
		Èmail: @kumc.edu
PhD	Professor, Department of	University of Kansas Medical
	Molecular and Integrative	Center
	Physiology	3901 Rainbow Blvd.
		Kansas City, Ks 66160 (913) 588-
Paul	Professor and Dept	Dept. Molecular and Integrative
	Molecular and Integrative	Physiology
	Physiology	University of Kansas Medical
		Center
		3901 Rainbow Blvd.
		Kansas City, Ks 66160
	Research Assistant	(913) 588- Department of OB/GYN
	Professor	University of Kansas Medical
		Center
		3901 Rainbow Blvd.
		Kansas City, Ks 66160
		(913) 588-1755
		Dece 22 of

	All redactions on th	nis page are pursuant to (b)(6) & (b)(7)(c).		
FOIA 10-549	·				32 of 241
			(402) 559	
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All redactions on this page are pursuant to (b)(6) & (b)(7)(c).

Case Number: KS09015-AC

Date: 02/18/10

CASE REPORT DISTRIBUTION (cc)

Program Official(s)

Dr. Robert Gibbens, Regional Director USDA, APHIS, AC 2150 Centre AVE. Bldg. B Mail stop #311 Fort Collins, CO 80526-8117 970-494-7474

IES Manager(s)

Larry Carson, Great Plains Area Manager USDA/ APHIS/ IES

CASE UPDATES

Program Official(s)

Dr. Robert Gibbens, Regional Director USDA, APHIS, AC Western Region Director, CO

Primary Investigator

USDA, APHIS, IES, Sr. Investigator 2150 Centre Ave. Building B 3W10 Fort Collins, CO 80526 (970) 494-(620) -202

FOIA 10-549 IES Area Manager

Larry Carson USDA, APHIS, IES 2150 Centre Ave. Building B 3W10 Fort Collins, CO 80526 (970) 494-7485

IES Deputy Regional Director

Eric Nickerson Deputy Regional Director USDA/ APHIS/ IES

IES Regional Director

Timothy Fordahl Western Regional Director USDA/ APHIS/ IES Г

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EXHIBIT LIST				
Exhibit #	Description	Date	Total Pages	
Exhibit 1	A copy of Registration letter and License Certificate with license number 48 R-0003	04/2707	2	
Exhibit 2	A copy of Annual Report of Research	04/17/09	1	
Exhibit 3	A copy of Division of the University of Kansas Center for Research	01/12/10	3	
Exhibit 4	A copy of University of Kansas Center for Research is registered with the Kansas Secretary of State	12/12/08	3	
Exhibit 5	A copy of Request for investigation	04/14/09	2	
Exhibit 6	A copy of USDA inspection Report	08/28/08	5	
Exhibit 7	A copy of Institutional Animal Care and Use Facility Review	12/18/07	27	
Exhibit 8	A copy of Institutional Animal Care and Use Facility Review	06/17/09	27	
Exhibit 9	Copies of photographs taken by Dr. Ziegerer	08/27/08	7	
Exhibit 10	Copies of photographs taken by Dr. Ziegerer	08/27/08	3	
Exhibit 11	Copies of photographs taken by Dr. Ziegerer	08/27/08	3	
Exhibit 12	Copies of photographs taken by Dr. Ziegerer	08/27/08	5	
Exhibit 13	A copy of USDA inspection Report	12/18/08	2	
Exhibit 14	A copy of University of Kansas Center for Research is registered with the Kansas Secretary of State	11/12/08	1	
Exhibit 15	A copy of Institutional Animal Care and Use Committee Minutes	05/20/08	10	
Exhibit 16	A copy of USDA inspection Report	03/10/09	29	
Exhibit 17	A copy of Institutional Animal Care and Use Committee Minutes	10/16/07	11	
Exhibit 18	A copy of Institutional Animal Care and Use Committee Minutes	11/20/07	12	
Exhibit 19	A copy of Animal Care and Use Proposal 2007- 1688	10/03/07	27	

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Exhibit 20	Copies of Laboratory Animal record # 1911	06/05/07, 06/06/07and 07/23/07,	8
Exhibit 21	Questionnaire answered by Dr.	12/11/09	8
Exhibit 22	A copy of Institutional Animal Care and Use Committee Minutes	03/24/08	10
Exhibit 23	A copy of Institutional Animal Care and Use Committee Minutes	04/14/08	23
Exhibit 24	A copy of Institutional Animal Care and Use Committee Minutes	05/20/08	10
Exhibit 25	A copy of Institutional Animal Care and Use Committee Minutes	06/17/08	8
Exhibit 26	A copy of Institutional Animal Care and Use Committee Minutes	07/15/08	6
Exhibit 27	A copy of Institutional Animal Care and Use Committee Minutes	08/19/08	11
Exhibit 28	A copy of Animal Care and Use Proposal 2007- 1686	10/03/07	18
Exhibit 29	Affidavit obtained from Dr. Katheryn Ziegerer	01/21/10	14
Exhibit 30	Questionnaire answered by	12/11/09	3
Exhibit 31	Copies of photographs taken by Tanya Tims SVMO	03/10/09	87
Exhibit 32	A copy of daily observation of animals Husbandry Room Checklists	2/20/09	6
Exhibit 33	A copy of Annual Report of Research	11/12/08	1
Exhibit 34	A copy of Amended Annual Report of Research	04/03/09	3
Exhibit 35	A copy of Amended Annual Report of Research	01/08/09	1
Exhibit 36	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	2
Exhibit 37	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	11
Exhibit 38	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	31
		<u> </u>	<u>_</u>

FOIA 10-549		:	<u>37 of 241</u>
Exhibit 39	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	13
Exhibit 40	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	8
Exhibit 41	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	18
Exhibit 42	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	50
Exhibit 43	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	7
Exhibit 44	A copy of photograph taken by Tanya Tims, SVMO	03/10/09	1
Exhibit 45	A copy of SOP PROG 8	N/A	5
Exhibit 46	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	15
Exhibit 47	A copy of Institutional Animal Care and Use Committee Minutes	09/16/08	9
Exhibit 48	A copy of photograph taken by Tanya Tims, SVMO	03/10/09	1
Exhibit 49	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	3
Exhibit 50	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	8
Exhibit 51	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	2
Exhibit 52	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	2
Exhibit 53	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	4
Exhibit 54	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	3
Exhibit 55	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	15

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Exhibit 56	A copy of USDA inspection Report	04/14/09	17
Exhibit 57	A copy of Animal Care and Use Proposal 2008- 1735	05/08/08	37
Exhibit 58	A copy of Animal Care and Use Proposal 2007- 1703	15/05/07	14
Exhibit 59	A copy of Animal Care and Use Proposal 2007- 1680	09/04/07	18
Exhibit 60	Questionnaire answered by Paul	12/11/09	14
Exhibit 61	Questionnaire answered by	12/11/09	6
Exhibit 62	Questionnaire answered by	12/11/09	9
Exhibit 63	Copies of LAR Training Record	12/12/06	5
Exhibit 64	Copies of Lab Animal Records B5-AL11 and B4- 2A0 and B2-4A4 and A5-3A5 and A2-5A9 and C1-57Z and C2-5A	12/11/07	7
Exhibit 65	A copy of SOP PROG 5 Personnel Training	3/09	5
Exhibit 66	A copy of Principal Investigator	03/02/07	19
Exhibit 67	Copies of photographs taken by Ruth Bakker, VMO	04/14/09	18
Exhibit 68	Copies of Laboratory Animal Record for #99R1027	10/14/08 and 12/07/08	5
Exhibit 69	Copies of Animal Records for animal OAO	10/07/08, 10/15/08and 10/16/08	4
Exhibit 70	Copies of Emails with concerns for animal 0A0	10/08 and 1016/08	2
Exhibit 71	Copy of Primate Master record for 0A0	12/21/07	1
Exhibit 72	Copies of Laboratory Animal Record for 3A0	10/07/08, 10/09/08 and 10/10/08	3
Exhibit 73	Copies of Emails with concerns for animal 3A0	10/09/08 and 10/10/08	2
Exhibit 74	A copy of Animal record for animal 3A0	10/20/08	1
Exhibit 75	Primate Mater Record for animal 99R1027	01/01/07	1

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014 40 540			00 10:
01A 10-549 Exhibit 76	Primate Mater Record for animal 674	11/04	1 39 of 241
Exhibit 77	Primate Mater Record for animal 622	5/18/09	1
Exhibit 78	Primate Mater Record for animal 702	05/15/09	1
Exhibit 79	Primate Mater Record for animal 668	5/15/09	1
Exhibit 80	Primate Mater Record for animal 695	5/20/09	1
Exhibit 81	Copies of photographs taken by Ruth Bakker, VMO	04/14/09	2
Exhibit 82	Copies of photographs taken by Ruth Bakker, VMO	04/14/09	2
Exhibit 83	Copies of photographs taken by Ruth Bakker, VMO	04/14/09	3
Exhibit 84	Copies of photographs taken by Ruth Bakker, VMO	04/14/09	2
Exhibit 85	A copy of SOP HUSB 1 Food, Water and Bedding Management	04/09	11
Exhibit 86	Copies of photographs taken by Ruth Bakker, VMO	04/14/09	2
Exhibit 87	Copies of photographs taken by Ruth Bakker, VMO	04/14/09	3
Exhibit 88	A copy of SOP Prog 8 Promotion of Psychological Well Being of Non-human Primates	N/A	14
Exhibit 89	Copies of photographs taken by Ruth Bakker, VMO	04/14/09	26
Exhibit 90	Copy of video taken by Ruth Bakker, VMO	04/14/09	1
Exhibit 91	Exhibit 91 Copies of photographs taken by Ruth Bakker, VMO		2
Exhibit 92	A copy of USDA Inspection Report	06/30/09	5
Exhibit 93	A copy of Animal Care and Use Proposal 2007- 1619	01/05	12
Exhibit 94	A copy of Animal Care and Use Proposal 2006-	01/05	14

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Exhibit 95	Questionnaire answered by Culley, Veterinarian	12/11/09	3
Exhibit 96	Questionnaire answered by	12/11/09	3
Exhibit 97	A copy of Animal Care and Use Proposal 2009- 1796	04/13/09	38
Exhibit 98	Copies of MRI Scan Procedures	06/22/09	9
Exhibit 99	A copy of Treatment Record for animal AV82	05/20/09	1
Exhibit 100	A copy of Treatment Record for animal 5A9	06/19/09	1
Exhibit 101	A copy of Treatment Record for animal 5A3	06/19/09	1
Exhibit 102	A copy of Treatment Record for animal 702	6/19/09	1
Exhibit 103	A copy of Treatment Record for animal 3A1	06/19/09	1
Exhibit 104	A copy of Treatment Record for animal 99R1837	05/29/09	1
Exhibit 105	Laboratory Animal Record for 11F	05/06/09	2
Exhibit 106	Affidavit obtained from Dr. Tanya Tims	07/25/09	1
Exhibit 107	Affidavit obtained from Dr. Jami Niemann	08/05/09	1
Exhibit 108	Affidavit obtained from Dr. Ruth Bakker	11/30/09	2
Exhibit 109	Questionnaire answered by DVM	12/11/09	27
Exhibit 110	Questionnaire answered by	12/11/09	108
Exhibit 111	Questionnaire answered by	12/11/09	37
Exhibit 112	E mails from Thomas Field (UKMC Interim Associate Vice Chancellor for Compliance)	10/22/09 7 10/25/09	4
Exhibit 113	Email from Thomas Field (UKMC Interim Associate Vice Chancellor for Compliance)	12/11/09	1
Exhibit 114	Attachments received from KU Med Center	12/14/09	221
Exhibit 115	Interview Log by IES	12/18/09	1
Exhibit 116	A copy of Annual Report of Research	11/30/09	10

FOIA 10-549

United States

Department of

Animal and Plant

Health Inspection

2150 Centre Ave.

Phone: 970-494-7478 Fax: 970/494-7461

Agriculture

Animal Care Western Region

Building B Mail Stop # 3W11 Ft. Collins, CO 80526

Service

RE: ACKNOWLEDGEMENT OF UPDATE Certificate Number: 48-R-0003 Anniversary Date: 05/04/2013

> April 26, 2010 Customer ID Number: 1460

University Of Kansas Medical Center 3901 Rainbow Blvd 1040 Wescoe Pavilion - Ms 2014 Kansas City, KS_66160

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.

redactions on this page are pursuant to (b)(6) & (b)(7)(c)

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,

Koher Thefiliam

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

cc: D.V.M.

Enclosures



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

An Equal Opportunity Provider and Employer

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United States

SDA

Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service **Animal Care**

This is to certify that

is a registered under the

Animal Welfare Act

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

Certificate No.

Customer No.

Charles & Shipson

Deputy Administrator

All redactions on this page are pursuant to (b)(6) & (b)(7)(c).	
FOIA 10-549		43 of 241
very research facility, exhibitor, carrier, and intermediate handler not required to be licensed under ection 3 of the Animal Welfare Act, shall register with the USDA (7 USC 2136). This application ovides 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 C Applicant should send completed form 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 48-R-0003	
	1460	4-May-2010
1. REGISTRANT (Name and permanent mailing address, including Zip Code)	2. LOCATION (S) OF BUSINESS, EXHIBITION S (Use additional sheets if necessary)	TIE(s), OR RESEARCH FACILITIES
JNIVERSITY OF KANSAS MEDICAL CENTER 3901 Rainbow Blvd 1040 Wescoe Pavilion - Ms 2014 Kansas City, KS 66160	3901 Rainbow Boulevard Kansas City, KS 66160 County: WYANDOTTE	
оинту: WYANDOTTE теlephone (913) - 588 - 7015 -		
. (A) PREVIOUS USDA REGISTRATION NUMBER (IF ANY)	4. (B) ACTIVE USDA CERTIFICATE NUMBER(S) IN WHICH YOU HAVE AN INTEREST:
ARE YOU USING FEDERAL FUNDS TO CARRY OUT 6. TYPE OF REG	ISTRATION:	
RESEARCH, TESTS, OR EXPERIMENTS	Exhibitor 🗌 Class H – Inte	ermediate Handler
Yes 🗆 No 🔀 Class R –	Research Facility 🛛 Class T - Can	rier
. FEDERAL FUND TYPES: 8. TYPE OF ORG	ANIZATION:	<u></u>
Award X Contract X Grant Loan Dertners		Individual
9. IF INDIVIDUAL IDENTIFY EACH OWNER, IF PARTNERSHIP IDENTIFY EACH PAR OFFICERS FOR RESEARCH FACILITIES INCLUDE THE INSTITUTIONAL OFFICIAL		RINCIPAL
NAME B. TITLE	C. ADDRESS (Iull address, I	ncluding ZIP Code)
	· .	
CERTIFICA		
hereby register as a Research Facility, Exhibitor, Carrier, or Intermediate Handler under the Animal Wel o the best of my knowledge. I hereby acknowledge receipt of and agree to comply with all the regulations	fare Act. 7 U.S.C., 2131 ef seq. and I certify that the info s and standards contained in 9 CFR, Subpart A, parts 1.	rmation provided herein is true and corre 2 and 3.1 certify that all listed persons an
8 years of age or older	NAME AND TITLE (Type or Print)	12. DATE SIGNED
ACKNOWLEDGEMENT OF RECEIPT OF		4-9-12

APR 1 6 2010

FOIA 10-549



April 8, 2010

Robert Gibbens, DVM, Regional Director United States Department of Agriculture Animal and Plant Health and Inspection Service Animal Care – Western Region 2150 Centre Avenue, Building B, Mail Stop # 3W11 Fort Collins, CO 80526

Regarding:

University of Kansas Medical Center Certificate No.: 48-R-0003 Customer No.: 1460 44 of 241

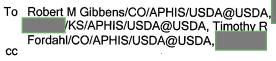
2010

Dear Dr. Gibbens:

Attached, please find an Application for Registration and a document entitled IMPORTANT for the University of Kansas Medical Center. Please note one correction to the phone number listed in section 1 of the application. The correct phone number is (913) 588 – III you have any questions, please contact me at (913) 588 – III you have and the section of the application.

Sincerely,





bcc

Subject KS09015-AC

University of Kansas Medical Center has been sent a Stip for \$62,500. Attached is copies of the Settlement Agreement and Cover Letter. If you have any questions, please contact Roxanne Folk, 301-734-5578.





ks09015 u of kansas med ctr sag.doc KS09015-AC University of Kansas Medical Center Ltr.doc KS09015-AC UKMC scanned.pdf

Certified Mail Tracking Number: 70093410000185220471

Thank vou.

US Department of Agriculture Animal and Plant Health Inspection Service Investigative and Enforcement Services- Headquarters (301)734-

@aphis.usda.gov

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SENDER: COMPLETE THIS SECTION	COMPLETE THIS SECTION ON DELIVERY
 Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired. Print your name and address on the reverse so that we can return the card to you. Attachethis card to the back of the mailpiece, or the front if space permits. Article Addressed to: 	A. Signature (b)(6). (b)(7)(c)
University of Kansas Medical Cente	er :
3901 Rainbow Blvd. 1040 Wescoe Pavillion – MS2014 Kansas City, KS 66160	3. Service Type Image: Certified Mail Image: Express Mail Image: Certified Mail Image: Certified Mail Image: Certified Mail Image: Certified Certified Mail Image: Certified Mail Image: Certified C
	4. Restricted Delivery? (Extra Fee)
2. Article Number 7009 (Transfer from service label)	3410 0001 8522 0471
PS Form 3811, February 2004 Domestic Re	turn Receipt 102595-02-M-1540

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, 2410 000 014E	Postage Certified Fee Return Receipt Fee (Endorsement Required) Restricted Delivery Fee (Endorsement Required) Total Postage & Fees	\$APR 1	2 8 20	10	Postmark Here
6002	Sent To Street, Apt. No.; or PO Box No. City, State, ZIP+4 PS Form 3800. August 2	XX91C	215-1	K.	See Reverse for Instructions

All redactions on this page are pursuant to (b)(6) & (b)(7)(c).



APR 2 8 2010

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CERTIFIED MAIL RETURN RECEIPT

United States Department of Agriculture

Animal and Plant Health Inspection Service

Marketing & Regulatory Programs Business Services

4700 River Road Riverdale, MD 20737 3901 Rainbow Blvd. 1040 Wescoe Pavillion – MS2014 Kansas City, KS 66160

University of Kansas Medical Center

Dear Sir(s):

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

Our investigation shows that you have violated the United States Code of Federal Regulations as described on the enclosed Stipulation. APHIS laws and regulations provide for administrative and criminal penalties to enforce these regulatory requirements, including civil penalties of \$125,000 for the violations documented in our investigation.

The Secretary of Agriculture may, after providing notice and opportunity for a hearing, impose civil penalties or other sanctions. You may, however, waive your right to a hearing and settle this matter by paying \$62,500 by June 07, 2010 and signing the enclosed Stipulation.

Please pay the \$62,500 penalty by certified check or money order made payable to the Treasurer of the United States. Write the Case Number (KS09015-AC) on your check or money order and mail it with the signed Stipulation to:

USDA, APHIS, (General) (KS09015-AC) P. O. Box 979043 St. Louis, MO 63197-9000

If we do not receive your signed stipulation agreement and payment or notice that you wish to exercise your right to a hearing by June 07, 2010, this matter will be forwarded to the Department's Office of the General Counsel (OGC) for litigation. Please know that the penalty offered in this Stipulation represents a fraction of the civil penalty APHIS may seek should we refer this matter to OGC. You may contact our office at telephone number (301) 734-8684 if you have any questions.

Sincerely,

Bernadette Juarez

Enclosure

	cc:	R. Gibbens, AC, WR	<u>T. Fordahl, IES, WR</u>	L IES, WR
		IES, KS	AC, WR	
	APHIS:IE	S:DJarvis:ldh:734-6169:04/27/10:i:DCS	KS09015-AC University o	f Kansas Medical Center Ltr.
ŝ		rding American Agriculture		Certified Rev 2 (10-20-08)
	APHIS is	s an agency of USDA's Marketing and Regulate	ory Program	· · · ·

An Equal Opportunity Provider and Employer

FOIA 10-549 Investigative and Enforcement Services USDA, APHIS, IES 4700 River Road, Unit 85 Riverdale, MD 20737 Phone: (301) 734-8684 Fax: (301) 734-4328		ement Services	• 48 of 241 Settlement Agreement
RESPONDENT: University of 3901 Rainbo	f Kansas Madia Dw Błyd. e Pavillion – M		CASE NUMBER DUE ON OR BEFORE CONTACT PHONE (301) 734-
DATE	CITATION		DESCRIPTION
			See Attached Pages (Page 1 of 7)
PENALTY	\$ 62,500.	TERMS	
Prior to the issua to resolve the ab	hearing, to impose c ance of a formal comp ove-described violati	ivil penalties and other sa	Secretary of Agriculture, after providing notice and inctions to resolve violations. Inder the Act, The Department may enter into a stipulation titutes a waiver of your right to a hearing, a finding that the ns.

All redactions on this page are pursuant to (b)(6) & (b)(7)(c). All records are being withheld pursuant to (b)(7)(c)

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

Signature	of Res	pondent:
-----------	--------	----------

Date:

PAYMENT RECORD - FOR IES USE ONLY

Payment Type	Date	Amount	Signature of IES Representative

T04 – Settlement Agreement Revised 11/15/05 DATEFOIA 10-549

<u>CITATION</u> 9 CFR

DESCRIPTION

10-MAR-2009

2.31(d)(2)(iv)(B)

2.33(b)(2)

Institutional Animal Care and Use Committee (IACUC). For protocol 2007:1688 failed to include planning and consultation with the attending veterinarian on procedures that may cause more than momentary or slight pain and/or distress to animals.

Attending Veterinarian and Adequate Veterinary Care. Failed to establish and maintain adequate programs of veterinary care that included the use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care. APHIS observed the following: 1) An investigator cart in procedure room that contained expired drugs (8 vials) of ketamine (expiration

date 6/08) and one bottle of Nembutal Sodium Solution/Pentobarbital 50 mg/ml (exp. 9/1/08) also, butterfly catheters were stored in a drawer with an aerosol can of "Clippercide" spray. 2) In procedure room housing 4 macaques, a bottle of children's chewable vitamins were stored immediately adjacent to cleaning solutions. 3) In room an oral pill dispenser was observed being stored in a container with grooming supplies including nail clippers and a comb. A large white rabbit was observed with a persistent, abnormal head tilt to the right. 4) In room , an oral dispensing tube of Panacur (Fenbendazole) was being stored on a soap dispenser adjacent to cleaning chemicals. 5) A macaque was observed with red to brown colored crusty discharge around the resin on his surgically placed acrylic head cap. 6) Twenty six nonhuman primates were observed to have hair loss and/or excessive scratching.

2.33(b)(3)

3.56(c)

Attending Veterinarian and Adequate Veterinary Care.

Failed to establish and maintain adequate programs of veterinary care that included the daily observation of all animals to assess their health and well-being. APHIS observed several animals that had medical problems that had not been documented by animal caretakers nor communicated to the veterinary staff including a white rabbit (in room with a persistent, abnormal head tilt to the right; twenty six non human primates with varying amounts of hair loss and excessive scratching, including one animal that was thin.

Sanitation. Housekeeping. Failed to keep premises (building and grounds) clean and in good repair in order to protect animals from injury and to facilitate prescribed husbandry practices. The refrigerator room was observed with a thick layer of brown to tan dusty material on top. There was also a large quantity of spilled bedding present. In room was an uncovered trash can containing waste material.

2

DATE FOIA 10-549



DESCRIPTION

All redactions on this page are pursuant to (b)(2)High & (b)(7)(F)

10-MAR-2009

3.75(a)

3.75(c)(1)

3.75(f)

3.81(c)(2)

Housing Facilities, general. Structure. Construction.

Failed to provide housing facilities for nonhuman primates that are designed and constructed to be structurally sound, kept in good repair, and to protect the animals from injury. APHIS observed cages (18 squirrel monkeys) in room had a two inch by four inch opening at the front of the enclosures risking injury to the animal. The following non human primate rooms had drain covers that had been removed for cleaning and not replaced: room (2 squirrel monkeys); room (4 macaques); room (17 squirrel monkeys); room (11 squirrel monkeys in front, 11 in back); and room (18 squirrel monkeys).

Housing Facilities, general. Surfaces. General Requirements. Failed to provide surfaces in housing facilities that are constructed in a manner and made of materials that allow them to be readily cleaned and sanitized, or removed or replaced when worn or soiled. In room (housing 10 macaques), the drywall behind the hose was observed bowing out and had a roughened surface with peeling paint. This area is no longer impervious to moisture and can no longer be effectively cleaned and sanitized.

Housing Facilities, general. Drainage and waste disposal.

Failed to provide for regular and frequent collection, removal, and disposal of animal and food wastes, bedding, dead animals, debris, garbage, water, and any other fluids and wastes, in a manner that minimizes contamination and disease risk. APHIS observed several rooms housing nonhuman primates in which the trash cans were not covered. Rooms with uncovered or partially uncovered trash cans included: (4 macaques), (10 macagues), (6 macaques), and two trash cans on the dirty side of a cage wash used to clean nonhuman primate enclosures. Standing water was observed in the following rooms (housing 16 squirrel monkeys), room (housing 18 squirrel monkeys), room (housing 10 macaques); and room (housing 3 macagues) standing water was observed on the bottom shelf of the television cart.

Environment Enhancement to Promote Psychological Well-Being. Special considerations. Failed to provide special attention regarding enhancement of environment, based on the needs of the individual species and in accordance with the instructions of the attending veterinarian. Twenty-six nonhuman primates had variable degrees of hair loss ranging from partial to full loss of hair on the tail to patchy hair loss on the body. An additional seven nonhuman primates were observed by APHIS to be actively picking or stripping hair from their bodies or exhibiting stereotypic behaviors such as flipping or swaying.

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All redactions on	this page are	pursuant to	(b)(2)Hiah	(b)(7)(F)

DATE^{EOIA 10-549} 51 of 241 CITATION DESCRIPTION 9 CFR 10-MAR-2009 3.81(e)(2) Environment Enhancement to Promote Psychological Well-Being. Failed to appropriately exempt animals from the environmental enrichment plan. The committee approved an exemption to environment enhancement for squirrel monkeys on protocol 2007:1688; but the IACUC has not approved this exemption on an individual basis. Several squirrel monkeys had variable degrees of hair loss, which can be a sign of psychological distress. 3.82(a)Feeding. Failed to provide a diet of food that is clean, wholesome, palatable to the animals, of sufficient nutritive value for non human primates that is appropriate for the species, size, age, condition of the animal, and for the conditions in which the nonhuman primate is maintained. APHIS officials observed three containers of baby food used as treats for non human primates in the investigator lab in room These containers of food were expired. 19-APR-2009 2.31(d)(5) Institutional Animal Care and Use Committee (IACUC). Failed to conduct continuing review of activities at appropriate intervals as determined by the IACUC. Protocol 2007-1703; Protocol 2008-1735; and Protocol 2007-1680. 2.31(e)(4)Institutional Animal Care and Use Committee (IACUC). Failed to have a sufficiently detailed description of the procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable. Protocol 2007-1703, a guinea pig protocol, includes conflicting information concerning the dose and/or route of administration of anesthetic and analgesic drugs. 2.33(b)(2) Attending Veterinarian and Adequate Veterinary Care. Failed to establish and maintain adequate programs of veterinary care that included the use of appropriate methods to prevent. control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care. APHIS officials observed the following: 1) two squirrel monkeys (ID#668 and ID#702) wearing beaded metal collars that were rusty; 2) Macaque (ID#99R1027) was prescribed acetaminophen, but was given ibuprofen instead; 3) Medical records for a male macaque (ID#99R1027) stated that the chamber had not been cleaned in 3 weeks; 4) Medical records for macaque (ID#0A0) do not document that any veterinarian performed any evaluations, physical examinations, diagnosis, or developed any treatment plan from 10/07/08 through 10/16/08; and 5) In protocol 2008-1735 failed to weigh monkeys on a regular basis to check for normal weight gain as stated in the protocol.

	All redactions on this pag	e are pursuant to (b)(2)High & (b)(7)(F)
DATE FOIA 10-549	<u>CITATION</u> 9 CFR	DESCRIPTION 52 of 241
14-APR-2009	2.33(b)(3)	Attending Veterinarian and Adequate Veterinary Care. Failed to establish and maintain adequate programs of veterinary care that included the daily observation of all animals to assess their health and well-being. Checklists reviewed at this inspection showed that completion of daily observations (health check) were not documented on four occasions; all of which were on the weekend; Room (April 11 and April 12); Room (April 4 and April 5).
	3.75(c)(1)	Housing Facilities, General. Surfaces. Failed to have facilities made of materials that allow them to be readily cleaned and sanitized as required. In room housing 15 squirrel monkeys, there were areas of chipping and peeling paint on the wall in at least two areas exposing the bare cinder blocks which cannot be effectively cleaned and sanitized.
	3.75(c)(1)(i)	Housing Facilities, General. Surfaces. Failed to have fixtures constructed of materials that allow them to be readily cleaned and sanitized as required and free of excessive rust. A metal hook on one of the straps used to secure the perches in a squirrel monkey enclosure had rusted to the point that it could no longer be effectively cleaned and sanitized.
	3.75(e)	Housing Facilities, General. Storage. Failed to store supplies of food and bedding in a manner that protects the supplies from spoilage, contamination, and vermin infestation. A pallet of bedding in the second floor storage room, used to store primate feed and other animal supplies was stored against the wall, preventing the required cleaning (SOP HUSB 1 Food, Water, and Bedding Management).
	3.81(b)	Environment Enhancement to Promote Psychological Well- Being. Failed to develop and follow a program of monitoring and maintenance to ensure that all enrichment items for nonhuman primates are kept in good repair and can be effectively cleaned and sanitized. At least 4 metal circular discs, which are supposed to be reflective and act as mirrors to provide enrichment for the nonhuman primates were scratched to the point that the surface was no longer reflective. At least three "chew toys" observed to be chewed to the point that the surface was extremely grooved and pitted to the point that they could no longer be effectively cleaned and disinfected.

DATE FOIA 10-549	<u>CITATION</u> 9 CFR	DESCRIPTION	53 of 241
14-APR-2009	3.81(c)(2)	Environment Enhancement to Promote Ps Being. Special Considerations. Failed to p attention regarding enhancement of their envi the needs of the individual species and in acc instructions of the attending veterinarian. Se primates had variable degrees of hair loss ran full loss of hair on the tail to patchy hair loss were observed by APHIS to be actively picki of possible psychological distress.	rovide special ironment, based on ordance with the veral nonhuman nging from partial to on the body; several
	3.125(c)	Facilities, General. Storage. Failed to deve program that ensures that all supplies of food stored in facilities which adequately protect s deterioration, molding, or contamination by floor storage room used to store gerbil beddin with pallets of bedding leaving only a small of entrance of the room, preventing the required HUSB 1 Food, Water, and Bedding Manager	and bedding are such supplies from vermin. The ground ng was nearly filled open area at the I cleaning (SOP
30-JUN-2009	2.31(d)(5)	Institutional Animal Care and Use Comm Failed to conduct continuing review of activi intervals as determined by the IACUC. Inve 2008-1735 are not conducting animal activiti IACUC approved protocol. MRI anesthetic nonhuman primates will be tranquilized with laboratory written procedure for MRI utilized staff states that the animals are given a full d followed by a "Dormitor" for transport, which a ¹ / ₂ dose of ketamine every 30 minutes there	ties at appropriate stigators for Protocol ies as delineated in the procedures states that a ketamine. The d by the laboratory ose of ketamine ch is then followed by
	2.31(e)(2)	Institutional Animal Care and Use Comm Failed to ensure that all protocols include an for the number of animals to be use. Protoco contain a scientific justification for the appro- number of animals being used.	appropriate rationale ol 2009-1796 did not
	2.31(e)(3)	Institutional Animal Care and Use Comm Failed to provide a complete description of the animals to facilitate the evaluation of the proposed use of the animals.	he proposed use of the stocols by the IACUC.

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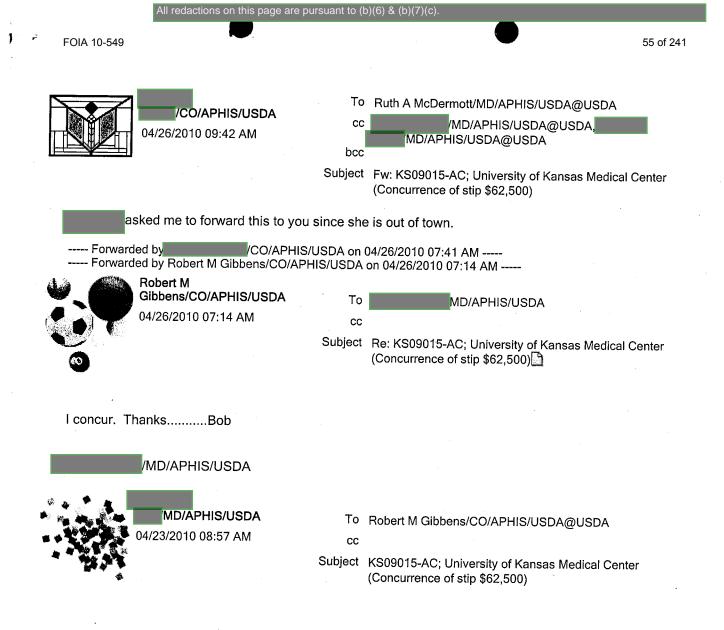
DESCRIPTION

30-JUN-2009

2.33(b)(2)

Attending Veterinarian and Adequate Veterinary Care.

Failed to establish and maintain adequate programs of veterinary care that included the use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care. Animal records showed that medications were not administered as prescribed by the veterinarian: Macaque #AV82- four missed doses of metronidazole; macaques #5A9, 5A3, 702, 3A1- missed one dose metronidazole; macaque #99R1837 missed one dose cephalexin; and squirrel monkey #11F - missed one dose "Rimadyl".



Hi,

We have reviewed case number KS09015-AC; University of Kansas Medical Center. This case documents findings from five AC inspections.

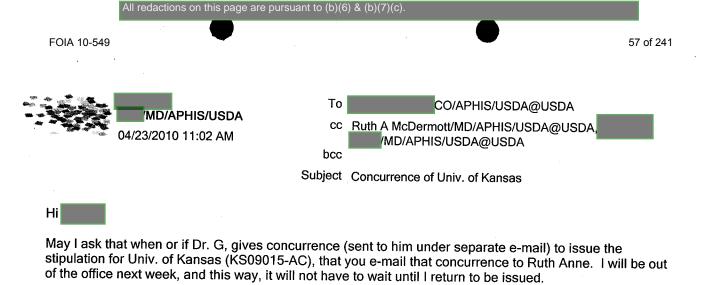
The stipulation calculates to \$ 62,500.

A reply with your concurrence is **required** to proceed with our recommended enforcement action.

A draft of the stipulation and penalty worksheets are attached for your information, review, and concurrence.

[attachment "ks09015 univ of kansas med ctr wrksht final.xls" deleted by Robert M Gibbens/CO/APHIS/USDA] [attachment "ks09015 u of kansas med ctr sag.doc" deleted by Robert M Gibbens/CO/APHIS/USDA] Enforcement Specialist Animal Health and Welfare Review and Enforcement Section Investigative and Enforcement Services Animal and Plant Health Inspection Service U.S. Department of Agriculture 4700 River Road Unit 85 (Room 6B-02.7) Riverdale, Maryland 20737 (301) 734-(301) 734-(301) 734-4328 (facsimile) @aphis.usda.gov

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Thanks so much for help with this situation.

Enforcement Specialist Animal Health and Welfare Review and Enforcement Section Investigative and Enforcement Services Animal and Plant Health Inspection Service U.S. Department of Agriculture 4700 River Road Unit 85 (Room 6B-02.7) Riverdale, Maryland 20737 (301) 734-(301) 734-(301) 734-4328 (facsimile) @aphis.usda.gov

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	All redactions on this page ar	e pursuant to	(b)(6) & (b)(7)(c).	
FOIA 10-549				58 of 241
04/	MD/APHIS/USDA 23/2010 10:57 AM	To cc bcc	Robert M Gibbens/CO/APHIS/USDA@USDA	
		Subject	KS09015-AC; University of Kansas Medical Cent (Concurrence of stip \$62,500)	er

Hi,

We have reviewed case number KS09015-AC; University of Kansas Medical Center. This case documents findings from five AC inspections.

The stipulation calculates to \$ 62,500.

A reply with your concurrence is **required** to proceed with our recommended enforcement action.

A draft of the stipulation and penalty worksheets are attached for your information, review, and concurrence.





ks09015 univ of kansas med ctr wrksht final.xls ks09015 u of kansas med ctr sag.doc

Enforcement Specialist Animal Health and Welfare Review and Enforcement Section Investigative and Enforcement Services Animal and Plant Health Inspection Service U.S. Department of Agriculture 4700 River Road Unit 85 (Room 6B-02.7) Riverdale, Maryland 20737 (301) 734-(301) 734-(301) 734-@aphis.usda.gov

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، FOIA 10-5	All redactions on this page are pursuant to (b)(6) 4	& (b)(7)(c).
Investigativ USDA, APHIS, IE 4700 River Road, Riverdale, MD 20 Phone: (301) 734 Fax: (301) 734-43	Unit 85 737 I-8684	Settlement Agreement
3901 Rainboy	Pavillion – MS2014	CASE NUMBER DUE ON OR BEFORE CONTACT PHONE (301) 734
DATE	CITATION	
		See Attached Pages
Titles 7, 15, 19, ar	S TERMS Ind 21 of the United States Code authorize to earing, to impose civil penalties and other	he Secretary of Agriculture, after providing notice and sanctions to resolve violations.

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

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

Signature of Respondent:

Date:

PAYMENT RECORD - FOR IES USE ONLY

Payment Type	Date	Amount	Signature of IES Representative

T04 – Settlement Agreement Revised 11/15/05

All redactions on this page are pursuant to (b)(2)High $\underline{\&$ (b)(7)(F)}

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10-MAR-2009



a

CITATION

2.31(d)(2)(iv)(B)

9 CFR

2.33(b)(2)

2.33(b)(3)

3.56(c)

Wr r

DESCRIPTION

Institutional Animal Care and Use Committee (IACUC). For protocol 2007:1688 failed to include planning and consultation with the attending veterinarian on procedures that may cause more than momentary or slight pain and/or distress to animals.

Attending Veterinarian and Adequate Veterinary Care.

Failed to establish and maintain adequate programs of veterinary care that included the use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care. APHIS <u>observed</u> the following: 1) An investigator cart in procedure room

that contained expired drugs (8 vials) of ketamine (expiration date 6/08) and one bottle of Nembutal Sodium Solution/Pentobarbital 50 mg/ml (exp. 9/1/08) also, butterfly catheters were stored in a drawer with an aerosol can of "Clippercide" spray. 2) In procedure room housing 4 macaques, a bottle of children's chewable vitamins were stored immediately adjacent to cleaning solutions. 3) In room oral pill dispenser was observed being stored in a container with grooming supplies including nail clippers and a comb. A large white rabbit was observed with a persistent, abnormal head tilt to the right. 4) In room an oral dispensing tube of Panacur (Fenbendazole) was being stored on a soap dispenser adjacent to cleaning chemicals. 5) A macaque was observed with red to brown colored crusty discharge around the resin on his surgically placed acrylic head cap. 6) Twenty six nonhuman primates were observed to have hair loss and/or excessive scratching.

Attending Veterinarian and Adequate Veterinary Care.

Failed to establish and maintain adequate programs of veterinary care that included the daily observation of all animals to assess their health and well-being. APHIS observed several animals that had medical problems that had not been documented by animal caretakers nor communicated to the veterinary staff including a white rabbit (in room with a persistent, abnormal head tilt to the right; twenty six non human primates with varying amounts of hair loss and excessive scratching, including one animal that was thin.

Sanitation. Housekeeping. Failed to keep premises (building and grounds) clean and in good repair in order to protect animals from injury and to facilitate prescribed husbandry practices. The refrigerator room was observed with a thick layer of brown to tan dusty material on top. There was also a large quantity of spilled bedding present. In room there was an uncovered trash can containing waste material.

FOIA 10-549

DATE

10-MAR-2009

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CITATION

9 CFR

3.75(a)

3.75(c)(1)

3.75(f)

3.81(c)(2)

All redactions on this page are pursuant to (b)(2)High & (b)(7)(F)

DESCRIPTION

61 of 241

1 that

	Housing Facilities, general. Structure. Construction. Failed to provide housing facilities for nonhuman primates that is designed and constructed to be structurally sound, kept in good repair, and to protect the animals from injury. APHIS observed cages (18 squirrel monkeys) in room had a two inch by four inch opening at the front of the enclosures. The following non human primate rooms had drain covers that had been removed for cleaning and not replaced: room (2 squirrel monkeys); room (4 macaques); room (17 squirrel monkeys); room (11 squirrel monkeys in front, 11 in back); and room (18 squirrel monkeys).
	Housing Facilities, general. Surfaces. General Requirements. Failed to provide surfaces in housing facilities that are constructed in a manner and made of materials that allow them to be readily cleaned and sanitized, or removed or replaced when worn or soiled. In room (housing 10 macaques), the drywall behind the hose was observed bowing out and had a roughened surface with peeling paint. This area is no longer impervious to moisture and con no longer be effectively cleaned and sanitized.
Forteel	Housing Facilities, general. Drainage and waste disposal. Eiled to provide for regular and frequent collection, removal, and disposal of animal and food wastes, bedding, dead animals, debris, garbage, water, and any other fluids and wastes, in a manner that minimizes contamination and disease risk. APHIS observed the several rooms housing nonhuman primates in which the trashcans were not covered. Rooms with uncovered or partially uncovered trashcans included: (4,macaques), (10 macaques), (6 macaques), and two trashcans on the dirty side of a cage wash used to clean nonhuman primate enclosures. Standing water was observed in the following rooms (housing 16 squirrel monkeys), room (housing 18 squirrel monkeys), room (housing 10 macaques); and room (housing 3 macaques) standing water was observed on the bottom shelf of the television cart.
	Environment Enhancement to Promote Psychological Well-

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Environment Enhancement to Promote Psychological Well-

Being. Special considerations. Failed to provide special attention regarding enhancement of their environment, based on the needs of the individual species and in accordance with the instructions of the attending veterinarian. Twenty-six nonhuman primates had variable degrees of hair loss ranging from partial to full loss of hair on the tail to patchy hair loss on the body. An additional seven nonhuman primates were observed by APHIS to be actively picking or stripping hair from their bodies or exhibiting stereotypic behaviors such as flipping or swaying.

FOIA 10-549		62 of 241
DATE	<u>CITATION</u> 9 CFR	DESCRIPTION
10-MAR-2009 Č	3.81(e)(2)	Environment Enhancement to Promote Psychological Well-Being. Failed to appropriately exempt animals from the environmental enrichment plan. The committee approved an exemption to environment enhancement for squirrel monkeys on protocol 2007:1688; but the IACUC has not approved this exemption on an individual basis. Several squirrel monkeys had variable degrees of hair loss, which can be a sign of psychological distress.
	3.82(a)	Feeding. Failed to provide a diet of food that is clean, wholesome, palatable to the animals, of sufficient nutritive value for non human primates that is appropriate for the species, size, age, condition of the animal, and for the conditions in which the nonhuman primate is maintained. APHIS officials observed three containers of baby food used as treats for non human primates in the investigator lab in room G010. These containers of food were expired.
19-APR-2009	2.31(d)(5)	Institutional Animal Care and Use Committee (IACUC). Failed to conduct continuing review of activities at appropriate intervals as determined by the IACUC. Protocol 2007-1703; Protocol 2008-1735; and Protocol 2007-1680.
<i>ک</i>	2.31(e)(4)	Institutional Animal Care and Use Committee (IACUC). Failed to have a sufficiently detailed description of the procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable. Protocol 2007-1703, a guinea pig protocol, includes conflicting information concerning the dose and/or route of administration of anesthetic and analgesic drugs.
R	2.33(b)(2)	Attending Veterinarian and Adequate Veterinary Care. Failed to establish and maintain adequate programs of veterinary care that included the use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care. APHIS officials observed the following: 1) two squirrel monkeys (ID#668 and ID#702) were observed wearing beaded metal collars that were rusty; 2) Macaque (ID#99R1027) was prescribed acetaminophen, but was given ibuprofen instead; 3) Medical records for a male macaque (ID#99R1027) stated that the chamber had not been cleaned in 3 weeks; 4) Medical records for macaque (ID#0A0) do not document that any veterinarian performed any evaluations, physical examinations, diagnosis, or developed any treatment plan from 10/07/08 through 10/16/08; and 5) In protocol 2008-1735 failed to weigh monkeys on a regular basis to check for normal weight gain as stated in the protocol.

All redactions on this page are pursuant to (b)(2)High & (b)(7)(F)

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DATE	<u>CITATION</u> 9 CFR	DESCRIPTION
14-APR-2009	2.33(b)(3)	Attending Veterinarian and Adequate Veterinary Care. Failed to establish and maintain adequate programs of veterinary care that included the daily observation of all animals to assess their health and well-being. Checklists reviewed at this inspection showed that completion of daily observations (health check) were not documented on four occasions; all of which were on the weekend; Room (April 11 and April 12); Room (April 4 and April 5) no daily health check was documented.
Ċ	3.75(c)(1)	Housing Facilities, General. Surfaces. Failed to have facilities made of materials that allow them to be readily cleaned and sanitized as required. In room face housing 15 squirrel monkeys, there were areas of chipping and peeling paint on the wall in at least two areas exposing the bare cinder blocks which cannot be effectively cleaned and sanitized.
Ċ	3.75(c)(1)(i)	Housing Facilities, General. Surfaces. Failed to have fixtures constructed of materials that allow them to be readily cleaned and sanitized as required and free of excessive rust. A metal hook on one of the straps used to secure the perches in a squirrel monkey enclosure had rusted to the point that it could no longer be effectively cleaned and sanitized.
V	3.75(e)	Housing Facilities, General. Storage. Failed to store supplies of food and bedding in a manner that protects the supplies from spoilage, contamination, and vermin infestation. A pallet of bedding in the second floor storage room, used to store primate feed and other animal supplies was stored against the wall, preventing the required cleaning (SOP HUSB 1 Food, Water, and Bedding Management).
Y	3.81(b)	Environment Enhancement to Promote Psychological Well-Being. Failed to develop and follow a program of monitoring and maintenance to ensure that all enrichment items for nonhuman primates are kept in good repair and can be effectively cleaned and sanitized. At least 4 metal circular discs, which are supposed to be reflective and act as mirrors to provide enrichment for the nonhuman primates were scratched to the point that the surface was no longer reflective. At least three "chew toys" observed to be chewed to the point that the surface was extremely grooved and pitted to the point that they could no longer be effectively cleaned and disinfected.

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FOIA	10-549
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 DATE
 CITATION

 9 CFR

 14-APR-2009
 3.81(c)(2)

 J
 3.125(c)

 J
 J

 30-JUN-2009
 2.31(d)(5)

2.31(e)(2)

2.31(e)(3)

DESCRIPTION

Environment Enhancement to Promote Psychological Well-Being. Special Considerations. Failed to provide special attention regarding enhancement of their environment, based on the needs of the individual species and in accordance with the instructions of the attending veterinarian. Several nonhuman primates had variable degrees of hair loss ranging from partial to full loss of hair on the tail to patchy hair loss on the body; several were observed by APHIS to be actively picking and showing signs of possible psychological distress.

Facilities, General. Storage. Failed to develop and follow a program that ensures that all supplies of food and bedding are stored in facilities which adequately protect such supplies from deterioration, molding, or contamination by vermin. The ground floor storage room used to store gerbil bedding was nearly filled with pallets of bedding leaving only a small open area at the entrance of the room, preventing the required cleaning (SOP HUSB 1 Food, Water, and Bedding Management).

Institutional Animal Care and Use Committee (IACUC). Failed to conduct continuing review of activities at appropriate intervals as determined by the IACUC. Investigators for Protocol 2008-1735 are not conducting animal activities as delineated in the IACUC approved protocol. MRI anesthetic procedures states that nonhuman primates will be tranquilized with ketamine. The laboratory written procedure for MRI utilized by the laboratory staff states that the animals are given a full dose of ketamine followed by a "Dormitor" for transport, which is then followed by a $\frac{1}{2}$ dose of ketamine every 30 minutes thereafter.

Institutional Animal Care and Use Committee (IACUC). Failed to ensure that all protocols include an appropriate rationale for the number of animals to be use. Protocol 2009-1796 did not contain a scientific justification for the appropriateness of the number of animals being used.

Institutional Animal Care and Use Committee (IACUC). Failed to provide a complete description of the proposed use of the animals to facilitate the evaluation of the protocols by the IACUC. Protocol 2007-1680 did not contain a complete description of the proposed use of the animals. FOIA 10-549

DATE

30-JUN-2009

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,	<u>CITATION</u> 9 CFR
	2.33(b)(2)

DESCRIPTION

Attending Veterinarian and Adequate Veterinary Care.

Failed to establish and maintain adequate programs of veterinary care that included the use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care. Animal records showed that medications were not administered as prescribed by the veterinarian: Macaque #AV82- four missed doses of metronidazole; macaques #5A9, 5A3, 702, 3A1- missed one dose metronidazole; macaque #99R1837 missed one dose cephalexin; and squirrel monkey #11F - missed one dose "Rimadyl". A 1

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	Case Number KS09015-AC	T098 Animal Care Benalty Workshoot	
	(110 1035 that \$200)	Agency Supulation Recommendation:	\$62,500.00
)(2) high			
	Animal	Care Penalty Worksheet	

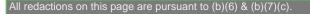
Univ. Of Kansas Med. Ctr. Wrksht final.

109B Animal Care Penalty Worksheet (Occurred on/after 6/18/08) Rev

10/9/08

. 97

Page 27 redacted for the following reason: (b)(2)High



FOIA 10-549

 Bernadette R
 To
 /MD/APHIS/USDA@USDA

 03/26/2010 01:54 PM
 Cc
 Robert M Gibbens/CO/APHIS/USDA@USDA

 bcc
 Subject
 Subject

Please review Dr. Gibbens' message below and see me when you have a moment.

Thanks, B. Bernadette Juarez, Deputy Director Investigative and Enforcement Services Animal and Plant Health Inspection Service U.S. Department of Agriculture 4700 River Road Unit 85 (Room 6B-03B) Riverdale, Maryland 20737 (301) 734-0884 (301) 734-0884 (301) 734-4328 (facsimile) bernadette.r.juarez@aphis.usda.gov ----- Forwarded by Bernadette R Juarez/MD/APHIS/USDA on 03/26/2010 01:53 PM -----



Robert M Gibbens/CO/APHIS/USDA 03/26/2010 01:00 PM

To Bernadette R Juarez/MD/APHIS/USDA@USDA

cc

Subject Fw: KS09015 - - University of Kansas Medical Center

Bernadette - - I tried to call, but figured you must be off today. I believe we chatted briefly about this case previously. KU would like to pay a stip and move on.

I reviewed the case, and came up with 63 substantiated allegations. As I plug that into the penalty chart, that amounts to a stip of \$78,750. KU would pay that amount (will probably pay anything under 80K or so). KU is interested in dispatching with this as quickly as possible. Let me know how you would like to proceed. I can forward this recommendation to Ruth Ann, as I normally would, or we can go some other route. I'm in Mon and Tues of next week......Bob

The investigative report documents the findings from 5 inspections in 2008 and 2009. Inasmuch as KU has no prior enforcement actions on file, repeat and direct NCIs should be used for sanction determination. The following are the alleged violations for sanction determination (note: all are supported by multiple APHIS witnesses and/or photos and/or other documentation):

<u>3/10/09</u> (39 counts)

2.31(d)(2)(iv)(B).....1 count (the attending veterinarian was not involved in the planning/consulting for procedures that may cause more than momentary or slight pain or distress **2.33(b)(2)**.....30 counts

All redactions on this page are pursuant to (b)(2)High & (b)(7)(F

FOIA 10-549

- outdated anesthetics stored/intermingled with pharmaceuticals that were currently being used
- oral pharmaceuticals that were being used were stored/intermingled with cleaning solutions (potential contamination)
- rabbit with head tilt
- macaque with discharge around head cap
- 26 NHPs with excessing scratching and/or hair loss...these animals had not been evaluated by a veterinarian

2.33(b)(3)....1 count (animals not being observed daily)

3.56(c)....1 count

receiving room, Room Room

3.75(a).....1 count

Room Drain covers

3.75(c)(1).....1 count (Room

3.75(f).....1 counts

uncovered trash cans in several animal rooms, standing water in several animal rooms and hallway
 3.81(c)(2)....1 count (failure to provide the 26 monkeys with hair loss/scratching mentioned in 2.33 above with special attention regarding enhancement of their environment)

3.81(e)(2)....1 count (failure to appropriately exempt animals from the environmental enrichment plan) 3.82(a)....1 count (use of expired baby food as treats - - some expired for over 1 year)

<u>4/14/09</u> (14 counts)

2.31(d)(1)(ii).....we cannot include this count, as we do not prevail here if our allegation is based on questioning the terms used for the search

2.31(d)(5).....1 count

Protocol 2007-1703, Protocol 2008-1735, Protocol 2007-1680

Section 2.31(e)(3).....I'm not counting the 3 protocols here as they were already counted under 2.31(d)(5) Section 2.31(e)(4)....1 count (conflicting information re dose and route of analgesia/anesthesia for Protocol 2007-1703)

2.33(b)(2).....5 counts

- rusted collars/frayed jackets for squirrel monkeys
- macaques given ibuprofen instead of acetaminophen
- cortical chamber not cleaned on macaque
- veterinary evaluations called for on 2007-1680 were not done
- failure to weigh animals on restricted diets (as called for)
- NOTE: we are not pursuing citations involving medical records 'only'
- 2.33(b)(3).....1 count (animals not being observed daily)

3.75(c)(1)....1 count (Room

- 3.75(c)(1)(i)....1 count (rusted squirrel monkey enclosure)
- 3.75(e)....1 count (bedding storage)

3.81(b).....1 count (enrichment items not maintained in good repair)

3.81(c)(2)....1 count (failure to provide the NHPs exhibiting signs of psychological distress with special attention regarding enhancement of their environment)

3.125(c)....1 count (storage of gerbil bedding)

6/30/09 (10 counts)

2.31(d)(1)(ii).....we cannot include this count, as we do not prevail here if our allegation is based on questioning the terms used for the search

2.31(d)(5)....1 count (Protocol 2008-1735)

Section 2.31(e)(2).....1 count (Protocol 2009-1796)

Section 2.31(e)(3)....1 count (Protocol 2007-1760)

2.33(b)(2).....7 counts (Medications not given as prescribed by the veterinarian)

- Macaque AV82
- Macaque 5A9
- Macaque 5A3
- Macaque 7O2
- Macaque 3A1



- Macaque 99R1837 Squirrel monkey 11F

Statutory Factors

Gravity = serious; given the high number of repeat noncompliances, the overall gravity is serious Size = large

Priors = none

Good faith = no evidence of good for or a lack of good faith

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RE: REGISTRATION UPDATE Certificate Number: 48-R-0003 Renewal Date: 05/04/2010

> February 26, 2010 Customer ID Number: 1460

USDA FOIA 10-549

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 Thomas R., Field, Msed, Mhsa University Of Kansas Medical Center 3901 Rainbow Blvd 1040 Wescoe Pavilion - Ms 2014 Kansas City, KS 66160

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,

Low Thefiliam

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

cc: Natalie Cooper, D.V.M.

Enclosures



Safeguarding American Agriculture APHIS is an agency of USDA's Marketing and Regulatory Programs All redactions on this page are pursuant to (b)(6) & (b)(7)(c)

FOIA 10-549

UNITED STATES DEPARTMENT OF AGRICULTURE

ANIMAL AND PLANT HEALTH INSPECTION SERVICE INVESTIGATIVE AND ENFORCEMENT SERVICES

REPORT OF INVESTIGATION

Case Number: KS09015-AC

(Contact Information)

Subject(s): University of Kansas Medical Center

Institutional

Official 3901 Rainbow Blvd 1040 Wescoe Pavillion - MS2014 Kansas City Kansas 66160 (913)-538-

Investigator:

(Contact Information)

USDA APHIS IES 2150 Centre Avenue Bldg B 3W10 Fort Collins Colorado 80526 970-494-620-202-

USDA APHIS IES 2150 Centre Avenue Bldg B 3W10 Fort Collins Colorado 80526 970-494 573-352

USDA APHIS IES 2150 Centre Avenue Bldg B 3W10 Fort Collins Colorado 80526 970-494 573-233

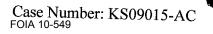
Date of Report: 02/18/10



Substantiated allegation(s)

No violation(s)

FOIA 10-549	 Insufficient evidence Fact finding Contains Confidential Business Information 	73 of 241
This docum without Reviewer(s)	FOR OFFICIAL USE ONLY nent and its contents are not to be distributed outside your agency, or dup t prior consent from USDA APHIS Investigative and Enforcement Service	licated, ces.



SYNOPSIS

USDA APHIS Animal Care conducted five inspections at the University of Kansas Medical Center (UKMC) Kansas City, Kansas on 8/27/08, 12/18/08, 3/10/09, 4/14/09, and 6/30/09. The USDA APHIS AC inspections document UKMC's failure to submit an Annual Report and their repeated failure to provide veterinary care; cleaning and facility maintenance; Institutional Animal Care Use Committee (IACUC) oversight, feeding, sanitation, drainage and waste disposal, primary enclosures, numerous violations that affect the psychological well being of nonhuman Primates, and an inadequate number of properly trained employees.

BACKGROUND

Subject(s) Information

UKMC is registered with USDA as a Research Facility with registration number 48-R-0003 (Fxhibit 1). UKMC's 2009 Annual Report to USDA lib6, b7c

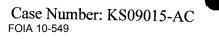
(<u>Exhibit 2</u>). UKMC is a Division of the University of Kansas Center for Research (<u>Exhibit 3</u>). The University of Kansas Center for Research is registered with the Kansas Secretary of State as a Not for Profit Corporation, corporation number 0031468 (<u>Exhibit 4</u>).

Subject(s) Previous History

Prior Enforcement Actions

A review of the IES Tracking System shows no previous history for UKMC.

Prior Adjudications N/A





Date: 02/1861041

NARRATIVE

Basis for Investigation

On 4/14/09, Dr. Robert Gibbens, Director Western Region USDA APHIS AC, requested USDA APHIS IES initiate an investigation of UKMC for: repeated failure to provide adequate veterinary care, repeated failure to properly clean and maintain facilities, numerous IACUC oversight violations, numerous violations that affect the psychological well-being of nonhuman Primates. and an inadequate number of properly trained employees (Exhibit 5).

Investigative Findings

August 27, 2008

On 8/27/08 Dr. Katheryn Ziegerer (USDA APHIS AC Veterinary Medical Officer (VMO)) and Dr. Jamilon Niemann (USDA APHIS AC VMO) conducted an inspection at UKMC (Exhibit 6) and documented the following non-compliant items:

UKMC – IACUC failed to provide a specific plan and schedule for correction dates on deficiencies identified in the IACUC Fall 2007 and Spring 2008 Facility Reviews (Exhibit 7-8).

Adequate Veterinary Care - UKMC failed to provide adequate veterinary care for nonhuman primates.

Feeding - UKMC failed to provide wholesome food for guinea pigs.

Housekeeping - UKMC failed to provide adequate housekeeping of rabbit housing facilities; Inspection Photographs (Exhibit 9).

Structure, Construction - UKMC failed to maintain the surfaces in nonhuman primate housing facilities; Inspection Photographs (<u>Exhibit 10</u>).

Surfaces, General Requirements - UKMC failed to maintain the surfaces of nonhuman primate housing facilities so that they were impervious to moisture. Inspection Photographs (Exhibit 11).

Drainage and Waste Disposal - UKMC failed to provide adequate drainage and waste disposal for necropsy samples and medications. Inspection Photographs (Exhibit 12).

Feeding - UKMC failed to provide wholesome for nonhuman primates as the enrichment foods being fed were expired.







On 12/18/08 Dr. Ziegerer conducted an inspection of UKMC (Exhibit 13). Dr. Ziegerer documented the UKMC Annual Report dated 11/12/08 (Exhibit 14 (Section 9.E) failed to include two exemptions to the AWA which had been approved by UKMC IACUC Committee (Exhibit 15 (Section 11.1 and 11.8.5).

March 10, 2009

On 3/10/09 Dr. Ziegerer and Dr. Tanya Tims (USDA APHIS AC Supervisory Veterinary Medical Officer (SVMO) conducted an inspection of UKMC (Exhibit 16) that documented the following non-compliant items:

UKMC IACUC – IACUC Committee Minutes dated 10/16/07 and 11/20/07(Exhibit 17 (Section 5.0) and Exhibit 18 (Section 6.0)) approved Protocol 2007-1688, the PI failed to include planning and consultation with the attending veterinarian on procedures that cause more than momentary or slight pain or distress to animals.

UKMC IACUC – IACUC Committee Minutes dated 10/16/07 and 11/20/07(Exhibit 17 (Section 5.0) and Exhibit 18 (Section 6.0)) approved Protocol 2007-1688 (Exhibit 19 (Section 6.1)) that failed to justify by scientific reason the use of an animal in more than one major operative procedure.

UKMC IACUC – IACUC Committee Minutes dated 10/16/07 and 11/20/07(Exhibit 17 (Section 5.0) and Exhibit 18 (Section 6.0)) approved Protocol 2007-1688 (Exhibit 19 (Section 6.1)) that failed to justify for scientific reasons procedures that may cause more than momentary or slight pain or distress to the animal.

UKMC IACUC failed to conduct appropriate reviews of animals activities to ensure the Protocol 2007-1688 (Exhibit 19 (Section 9.0)) manipulative environment enhancement exemption has not had a negative impact on the welfare of the animals: and failed to conduct appropriate reviews of animals activities to ensure the 10-30 minute monitoring of non-human primates that had transferred from the surgical table to the incubator Protocol 2007-1688 (Exhibit 19 (Section 6.3.5)) and Laboratory Animal Record #1911 (Exhibit 20). Principal Investigator Dr. (b)(6). (transferred (Exhibit 21)) to this item.

UKMC IACUC failed to make recommendations to the Institutional Official regarding any aspect of the animal facility. UKMC IACUC Meeting Minutes 3/24/08, 4/14/08, 5/20/08, 6/17/08, 7/15/08 and 8/19/08 (Exhibits 22-27) indicate increased research activity has exceeded the existing infrastructure;

UKMC IACUC failed to ensure the principal investigators for Protocol 2007-1688 (Exhibit 19 (Section 5.3)) and Protocol 2007-1686 (Exhibit 28 (Section 5.3)) considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animal. Dr. Ziegerer by affidavit (Exhibit 29) and Protocol 2007-1686 Principal Investigator Dr. (b)(6). (b) response (Exhibit 30) provide additional response to this item.

UKMC IACUC failed to ensure Protocol 2007-1688 (Exhibit 19 (Section 5.3, 6.3.4, 6.3.5)) was designed to assure that discomfort and pain to animals are limited in sufficient detail for the IACUC to

determine whether or not the procedures are adequate to protect the welfare of the animals780f241 EOIA 10-549 Ziegerer provides additional response to this item (Exhibit 29).

UKMC IACUC failed to ensure a complete description of the proposed use of the animals and is not specific on how many major survival surgeries each animal will undergo prior to euthanasia Protocol 2007-1688 (Exhibit 19 (Section 6.1)); Adequate Veterinary Care – documents numerous non-compliant veterinary care issues Inspection Photographs (Exhibit 31). Dr. Ziegerer provides additional response to this item (Exhibit 29).

Adequate Veterinary Care - UKMC failed to establish and maintain adequate programs of daily observation of animal Husbandry Room Checklists (Exhibit 32).

Annual Report – UKMC did not report any nonhuman primates on the Annual Report (<u>Exhibit 33</u>) upon which experiments, research, surgery, or tests were conducted involving pain or distress to the animals 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. UKMC Amended Annual Report 4/3/09 (<u>Exhibit 34</u>) and Protocol 2007-1688 (<u>Exhibit 19 (Section 5.3</u>)) documents inaccurate pain classifications.

Annual Report – UKMC did not report at least thirty two nonhuman primates on the annual report as being bred, conditioned or held (<u>Exhibit 33</u>). UKMC Amended Annual Report 4/3/09 (<u>Exhibit 34</u>) lists three dogs, five guinea pigs, twenty hamsters and twenty three nonhuman primates as being bred, conditioned or held. Dr. Ziegerer provides additional response to this item (<u>Exhibit 29</u>).

UKMC 2008 Annual Report Amendment (<u>Exhibit 35</u>) documents UKMC IACUC approved an exemption to housing standards to allow one nonhuman primate to be housed in an enclosure that did not meet minimum height requirements was in effect for approximately one month. IACUC Meeting Minutes March-May 2008 documents IACUC exemption approval more than one month (<u>Exhibit 23-25</u>).

Facilities, General – Structural Strength, Inspection Photographs (<u>Exhibit 36</u>) document UKMC failed to ensure housing facilities were kept in good repair.

Sanitation – Housekeeping, Inspection Photographs (<u>Exhibit 37</u>) document UKMC failed to keep facilities free of clutter, spilled feed, unused items, and open trash containers.

Sanitation – Pest Control; UKMC failed to have an adequate program for the control of insects.

Employees - UKMC failed to have appropriately trained employees in regards to proper sanitation practices.

Housing Facilities – Structure- Construction, Inspection Photographs (<u>Exhibit 38</u>); UKMC failed to maintain housing facilities for nonhuman primates which were structurally and protected the animals from injury.

Housing Facilities – Surfaces, Inspection Photographs (Exhibit 39); UKMC failed to maintain the surfaces of housing facilities in good repair and could be readily cleaned and sanitized.

Housing Facilities – Storage, Inspection Photographs (<u>Exhibit 40</u>); UKMC failed to property and food supplies.

Housing Facilities – Drainage/Waste Disposal, Inspection Photographs (<u>Exhibit 41</u>); UKMC failed to have adequate drainage and waste disposal systems to rapidly remove standing water.

Housing Facilities – Surfaces – Cleaning, Inspection Photographs (<u>Exhibit 42</u>); UKMC failed to adequately clean and sanitize housing facility surfaces and primary enclosures of nonhuman primates.

Housing Facilities – Surfaces, Inspection Photographs (<u>Exhibit 43</u>). UKMC failed to maintain housing facility surfaces which were free of rust and could be adequately cleaned and sanitized.

Primary Enclosures, Inspection Photographs (<u>Exhibit 44</u>); UKMC failed to provide the minimum space requirements for nonhuman primates. Dr. Ziegerer provides additional response to this item (<u>Exhibit 29</u>).

Environment Enhancement – Social Grouping, SOP PROG 8 (<u>Exhibit 45</u>); UKMC failed to address the group and social housing requirements for nonhuman primates which live in social groups in the wild.

Environment Enhancement – Environmental Enrichment, Inspection Photographs (<u>Exhibit 46</u>); UKMC failed to provide environmental enrichment items and toys which were in good repair.

Environment Enhancement – SOP PROG 8 (Exhibit 45) and Protocol 2007-1688 (Exhibit 19 (Section 9.0)). UKMC failed to provide adequate environment enhancement items for nonhuman primates.

Environment Enhancement – Special Considerations, SOP PROG 8 (<u>Exhibit 45</u>); UKMC failed to house nonhuman primates in a manner which allowed the animals to be visible to each other.

Environment Enhancement – Exemptions, Protocol 2007-1688 (Exhibit 19 (Section 9.0)) and IACUC Committee Meeting Minutes (Exhibit 47 and 23.); UKMC failed to approve environment enhancement exemptions on an individual animal basis and failed to review the exemptions to ensure animals were not negatively affected.

Environment Enhancement – Special Considerations; UKMC failed to develop and follow an enhancement plan for nonhuman primates which were exhibiting signs of psychological distress.

Feeding, Inspection Photographs (Exhibit 48); UKMC failed to provide wholesome food to nonhuman primates as treats being fed were past their expiration dates.

Sanitization, Inspection Photographs (<u>Exhibit 49</u>); UKMC failed to adequately sanitize primary enclosures as the cagewash was incapable of reaching 180 degrees F.

Housekeeping, Inspection Photographs (Exhibit 50); UKMC failed to provide adequate housekeeping in nonhuman primate housing facilities.

Pest Control, Inspection Photographs (Exhibit 51); UKMC failed to have an effective program for the control of rodents.

Employees; UKMC failed to have a sufficient number of adequately trained employees to provate for the proper care and handling of nonhuman primates.

Facilities – Storage, Inspection Photographs (Exhibit 52); UKMC failed to properly store supplies of hay.

Sanitation, Inspection Photographs (Exhibit 53); UKMC failed to adequately clean and sanitize gerbil enclosures as the cagewash was incapable of reaching 180 degrees F.

Pest Control, Inspection Photographs (<u>Exhibit 54</u>); UKMC failed to have an effective program for the control of pests in the gerbil storage room.

Housekeeping, Inspection Photographs (Exhibit 55); UKMC failed to provide adequate housekeeping in the housing facilities of gerbils.

Employees; UKMC failed to have a sufficient number of adequately trained employees to provide the professionally acceptable level of husbandry practices.

April 14, 2009

On 4/14/09 Dr. Ziegerer and Dr. Ruth Bakker (USDA APHIS AC VMO) conducted an inspection (Exhibit 56) at UKMC that documented the following non-compliant items:

UKMC IACUC – Protocol 2008-1735 (Exhibit 57 (Section 5.3)) and Protocol 2008-1703 (Exhibit 58 (Section 5.3)) and Protocol 2008-1680 (Exhibit 59 (Section 5.3)) do not include terms that relate to the procedures that may cause more than momentary or slight pain or distress to the animals. Protocol 2008-1735 Principal Investigator (Exhibit 60), Protocol 2008-1703 Principal Investigator (Exhibit 61). Protocol 2008-1680 Principal Investigator (Exhibit 62).

UKMC IACUC failed to ensure personnel conducting procedures on regulated species must be appropriately qualified and trained. Protocol 2008-1703 (Exhibit 58 (Section 6.9)), Protocol 2008-1703 Principal Investigator (and Research Assistant (Training Records (Exhibit 63) and response (Exhibit 61).

UKMC IACUC failed to conduct appropriate reviews of animal activities to ensure the principle investigators are conducting animal activities as delineated in Protocol 2007-1703 (Exhibit 58 (Section 5.3) (Section 6.3.3)(Section 6.9)), Protocol 2008-1735 (Exhibit 57 (Section 6.6)(Section 6.1)), Protocol 2008-1680 (Exhibit 59 (Section 6.1) (Section 6.4.2)(Section 6.5)), Lab Animal Records B5-AL11 andB4-2A0 and B2-4A4 and A5-3A5 and A2-5A9 and C1-57Z and C2-5A# (Exhibit 64), Protocol 2008-1703 Principal Investigator response (Exhibit 61), Protocol 2008-1735 Principal Investigator response (Exhibit 60), Protocol 2008-1680 Principal Investigator response (Exhibit 62). UKMC IACUC failed to ensure that all protocols include an appropriate rationale for the ruffber of Fola 10-549 animals to be used. Protocol 2007-1680 (Exhibit 59 (Section 5.3) (Section 6.1)) and Protocol 2008-1680 Principal Investigator response (Exhibit 62).

UKMC IACUC approved protocols that did not contain a complete description of the proposed use of the animals. Protocol 2008-1703 (<u>Exhibit 58</u>) and Protocol 2008-1703 Principal Investigator response (<u>Exhibit 61</u>). Protocol 2007-1680 (<u>Exhibit 59 (Section 6.1</u>)) and Protocol 2008-1680 Principal Investigator response (<u>Exhibit 62</u>), Protocol 2008-1735 (<u>Exhibit 57 (Section 6.1</u>)) and Protocol 2008-1735 Principal Investigator response (Exhibit 60).

UKMC IACUC – approved protocols that did not include a sufficiently detailed description of the procedures designed to assure that discomfort and pain to animals will be limited to animals to that which is unavoidable. Protocol 2007-1703 (Exhibit 58 (Section 6.3.5)) and Protocol 2008-1703 Principal Investigator response (Exhibit 61).

UKMC IACUC failed to ensure that all protocols to conduct an activity involving animals contain an appropriate description of the method of euthanasia to be used. Protocol 2008-1735 (Exhibit 57 (Section 6.9)(Section 12.0)(Section 6.1)) and Protocol 2008-1735 Principal Investigator response (Exhibit 60).

Personnel Qualification – UKMC failed to ensure all individuals involved in animal care, treatment and use must be qualified to perform their duties and appropriately trained. SOP 5 Personnel Training (Section 3.5) (<u>Exhibit 65</u>) and Protocol 2008-1735 Principal Investigator Training Record (<u>Exhibit 66</u>).

Adequate Veterinary Care; UKMC failed to maintain a program of adequate veterinary care that included the use of appropriate methods to prevent, control, diagnose and treat animals. Inspection Photographs (Exhibit 67), Laboratory Animal Record for #99R1027 dated 10/14/08 and 12/7/08 (Exhibit 68), Protocol 2008-1735 Principal Investigator response (Exhibit 60). Laboratory Animal Records #0A0 dated 10/7/08 and 10/15-17/08 (Exhibit 69), Research Assistant emails on #0A0 dated 10/8/08 and 10/16/08 (Exhibit 70), Investigator Records #0A0 dated 7/21/08 and 10/15/08 document a 22% weight loss (Exhibit 71), Laboratory Animal Records #3A0 dated 10/7/08, 10/9/08, 10/10/08 (Exhibit 72) and Principal Investigator and Research Assistant emails dated 10/9/08 and 10/10/08 (Exhibit 73) and #0A0 Medical Records (Exhibit 74) document the animal appears to have met the criteria for euthanasia days prior to being euthanized. Protocol 2007-1703 (Exhibit 58 (Section 6.3.6 and Section 6.5) and Protocol 2008-1703 Principal Investigator response (Exhibit 61) document failure to provide adequate veterinary care. Protocol 2008-1735 (Exhibit 57 (Section 6.1)) and Protocol 2008-1735 Principal Investigator response (Exhibit 60) document failure to provide and maintain adequate programs of veterinary care. Protocol 2008-1735 (Exhibit 57 (Section 6.7)), Primate Master Record #99R1027, #674, #622, #702, #668, #695 (Exhibits75-80) and Protocol 2008-1735 Principal Investigator response (Exhibit 60) document the lack of a system of health records of sufficiently

comprehensive to demonstrate the delivery of an adequate program of veterinary care.

Inspection Report (<u>Exhibit 56</u>) and Inspection Photographs (<u>Exhibit 81</u>) document UKMC failure of daily observation of all animals to assess their health and well being.

Miscellaneous – Handling, Protocol 2008-1735 (Exhibit 57 (Section 6.4.2)), Primate Master Breaord #99R1027 (Exhibit 75) and Protocol 2008-1735 Principal Investigator response (Exhibit 60) document UKMC IACUC failed to ensure adequate handling in respect to approved protocols.

Housing – Surfaces – Inspection Report (<u>Exhibit 56</u>) and Inspection Photographs (<u>Exhibit 82</u>) document UKMC failure of maintenance to ensure all surfaces are free of excessive rust.

Housing – Surfaces, Inspection Report (<u>Exhibit 56</u>) and Inspection Photographs (<u>Exhibit 83</u>) document UKMC failure of maintenance to ensure all surfaces to be readily cleaned and sanitized.

Housing – Storage – Inspection Report (<u>Exhibit 56</u>), Inspection Photographs (<u>Exhibit 84</u>) and SOP HUSB 1 Food, Water and Bedding Management (<u>Exhibit 85 (Section 4.2.7)</u>) document UKMC failure to store bedding in a manner that allows adequate cleaning.

Indoor Housing – Lighting, Inspection Report (<u>Exhibit 56</u>) and Inspection Photographs (<u>Exhibit 86</u>) document failure to provide adequate lighting to permit routine inspection.

Primary Enclosures – Inspection Report (Exhibit 56), Protocol 2007-1688 (Exhibit 19 (Section 10)) documents failure to provide sufficient volume of space.

Environment Enhancement – Inspection Report (<u>Exhibit 56</u>), Inspection Photographs (<u>Exhibit 87</u>) and SOP Prog 8 Promotion of Psychological Well Being of Non-human Primates (<u>Exhibit 88- page 3</u> (<u>Section 1(c)</u>) document UKMC failed to develop and follow a program of monitoring and maintenance to ensure all enrichment items are kept in good repair.

Environment Enhancement – Inspection Report (Exhibit 56), Inspection Photographs (Exhibit 89), Inspection Video (Exhibit 90) and SOP Prog 8 Promotion of Psychological Well Being of Non-human Primates (Exhibit 88) documents UKMC failure to develop and follow a plan to ensure nonhuman primates showing signs of psychological distress receive considerations with regard to enhancement;

Facilities – Storage, Inspection Report (<u>Exhibit 56</u>), Inspection Photograph (<u>Exhibit 91</u>) and SOP HUSB 1 Food, Water and Bedding Management (<u>Exhibit 85 (Section 4.2.7)</u>) document UKMC failure to store bedding in a manner that allows adequate cleaning.

June 30, 2009

On 6/30/09 Dr. Ziegerer and Dr. Niemann conducted an inspection (Exhibit 92) at UKMC that documented the following non-compliant items:

UKMC IACUC – Protocol 2007-1619 (Exhibit 93 (Section 19)) and Protocol 2006-1581 (Exhibit 94 (Section 19)) did not include terms that relate to the procedures that may cause more than momentary or slight pain or distress to the animals. Protocol 2007-1619 Principal Investigator Dr. (Exhibit 95) and Protocol Dr. 2006-1581 (Exhibit 96) respond to adequate alternatives or alternative methods to more than momentary or slight pain or distress to animals.

UKMC IACUC – Protocol 2007-1619 (Exhibit 93), Protocol 2006-1581 (Exhibit 94), Protocol 2009-1796 (Exhibit 97), Protocol 2007-1680 (Exhibit 59) and Dr. Ziegerer affidavit (Exhibit 29) document four protocols were reviewed and approved by a single member of the IACUC. UKMC IACUC – Protocol 2008-1735 (Exhibit 57 (Section 6.1 and 6.6)) and MRI Scan Proceedures (Exhibit 98) document Principal Investigators are not conducting animal activities as delegated in the approved protocol;

UKMC IACUC – protocol 2009-1796 (Exhibit 97 (Section 6.1 and Section 6.3)) and Dr. Ziegerer affidavit (Exhibit 29) document failure to contain scientific justification for the appropriateness of the number of animals being used.

UKMC IACUC – Protocol 2007-1680 (Exhibit 59 (Section 4.0) and Section 5.0 and Section 6.1)) document failure of the complete description of proposed use of animals;

Adequate Veterinary Care, Animal Treatment Records #AV82, #5A9, #5A3, #702, #3A1 and #99R1837 (Exhibits 99-104) document failure to provide adequate veterinary care; Adequate Veterinary Care, Laboratory Animal Record #11F (Exhibit 105) and Dr. Ziegerer (Exhibit 29) document failure to provide adequate veterinary care;

Indoor Housing Facilities – Lighting, Inspection Report (<u>Exhibit 92</u>) documents failure to provide adequate lighting to permit routine inspection.

On 7/29/09 Dr. Tanya Tims (USDA APHIS AC VMO) confirms assisting Dr. Ziegerer with a UKMC Inspection on 3/10/09 (Exhibit 106).

On 8/5/09 Dr. Jamilon Niemann (USDA APHIS AC VMO) confirms assisting Dr. Ziegerer with UKMC Inspections on 8/27/09 and 6/10/09 (Exhibit 107).

On 8/8/09 Investigator met with Thomas Field, Interim Associate Vice Chancellor for Compliance of UKMC and received documents that had been requested by IES, to be used as evidence to support the alleged violations (Exhibits 2, 4, 7, 8, 14, 15, 17, 18, 19, 21, 22, 23, 24, 25, 26, 27, 28, 30, 32, 33, 34, 35, 45, 47, 57, 58, 59, 66, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 85, 88, 93, 94 and 105).

On 10/21/2009, Investigatorcontacted Thomas Field, UKMC, by email with questionnaires to
be completed byDr.Dr.Dr.PI,PI,PI,PI andIACUC

Chair. On 12/11/09, Investigator received an email from Thomas Field containing the completed questionnaires (Exhibits 21, 30, 60, 61, 62, 95, 96, 109, 110 and 111).

E-mails (3) between (USDA APHIS IES) and Thomas Field UKMC responses to USDA Inspections of UKMC (Exhibit 112).

On 11/30/09 Dr. Ruth Bakker (USDA APHIS AC VMO) confirms assisting Dr. Ziegerer with UKMC Inspection on 4/14/09 (Exhibit 108).

On 12/11/09 Dr. (UKMC Attending Veterinarian) responded to questions posed by USDA APHIS IES relating to USDA APHIS AC Inspections conducted at UKMC on 8/27/08, 3/10/09, 4/14/09 and 6/30/09 (Exhibit 109).

On 12/11/09 Dr. (UKMC Vice Chancellor of Administration and UKMC Institutional Official) responded to questions posed by USDA APHIS IES relating to USDA APHIS AC Inspections conducted at UKMC on 8/27/08, 12/18/08, 3/10/09, 4/14/09 and 6/30/09 (Exhibit 110).

All redactions on this page are pursuant to (b)(6) & (b)(7)(c).

On 12/11/09 Dr. (UKMC IACUC Chairman) responded to questions posed by 1 USDA APHIS IES relating to USDA APHIS AC Inspections conducted at UKMC on 8/27/08, 3/10/09, 4/14/09 and 6/30/09 (Exhibit 111).

E-mail between (USDA APHIS IES) and (UKMC Vice Chancellor for Administration Institutional Official) relating to responses to USDA Inspections of UKMC (Exhibit 113).

On 12-14-09, Investigator received a package from Thomas Field, which contained the attachments that were referenced in Harold Phillips questionnaire (Exhibit114)

Interview Log prepared by IES, explaining why UKMC declined to sign affidavits (Exhibit 115).

These findings substantiate the following alleged violation(s):

9 C.F.R. § 2.31(c)(3) - IACUC functions.

On 8/27/09, UKMC failed to provide a specific plan and schedule for correction dates on deficiencies identified in the IACUC Fall 2007 and Spring 2008 Facility Review. This regulation requires, if program or facility deficiencies are noted the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency.

9 C.F.R. § 2.31(c)(5) – IACUC functions.

On 3/10/09, UKMC failed to make recommendations to the Institutional Official regarding increased research activity had exceeded the existing infrastructure creating a need for additional support for the Laboratory Animal Resources. This regulation requires the IACUC make recommendations to the Institutional Official regarding any aspect of the research facilities animal program, facilities or personnel training.

9 C.F.R § 2.31(d)(1)(ii) – IACUC review of activities involving animals.

On 3/10/09, 4/14/09, and 6/30/09, UKMC failed to include alternative terms that relate to the procedures that may cause more than momentary or slight pain or distress to the animals. This regulation requires the principal investigator consider alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and has a written narrative description of the methods and sources.

9 C.F.R § 2.31(d)(1)(iv)(A) – IACUC review of activities involving animals.

On 3/10/09, UKMC failed to justify for scientific reasons procedures that may cause more than momentary or slight pain or distress to the animal. This regulation requires procedures that may cause more than momentary or slight pain or distress to animals be performed with

appropriate sedatives, analgesics or anesthetics unless withholding such agents is justified for scientific reasons.

9 C.F.R. § 2.31(d)(1)(iv)(B) – IACUC review of activities involving animals.

On 3/10/09, UKMC failed to include planning and consultation with the attending veterinarian on procedures that cause more than momentary or slight pain or distress to animals. This regulation requires procedures that cause more than momentary or slight pain or distress to animals involve in their planning, consultation with the attending veterinarian.

9 C.F.R § 2.31(d)(1)(viii) - IACUC review of activities involving animals.

On 4/14/09, UKMC failed to ensure personnel conducting procedures on regulated species were appropriately qualified and trained. This regulation requires personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained on those procedures.

9 C.F.R. § 2.31(d)(1)(x) – IACUC review of activities involving animals.

On 3/10/09, UKMC failed to justify by scientific reason the use of at least one non-human primate that underwent three major survival surgeries. This regulation requires no animal will be used in more than one major operative procedure unless justified.

9 C.F.R § 2.31(d)(2) – IACUC review of activities involving animals.

On 6/10/09, UKMC allowed four protocols to be reviewed and approved by a single committee member without being available to all members for review and approval from each of the committee members. This regulation requires protocols shall be available to all IACUC members for review.

9 C.F.R § 2.31(d)(5) – IACUC review of activities involving animals.

On 3/10/09, 4/14/09 and 6/30/09, UKMC failed to conduct appropriate reviews of animal activities to ensure compliance with compliance with AWA Regulations and Standards. This regulation requires the IACUC shall conduct continuing reviews of activities covered by the AWA at appropriate intervals.

9 C.F.R. § 2.31(e)(2) - IACUC.

On 4/14/09 and 6/30/09, UKMC failed to ensure that all protocols include scientific justification for the appropriateness of the number of animals being used for research purposes. This regulation requires a scientific rationale for involving animals, and justification for numbers of animals being used.

9 C.F.R. § 2.31(e)(3) – IACUC.

On 3/10/09, 4/14/09, and 6/30/09, UKMC failed to ensure all proposals to conduct animal activities contain a complete description of proposed use of animals. This regulation requires a complete description of the proposed use of animals.

9 C.F.R. § 2.31(e)(4) – IACUC.

On 3/10/09 and 4/14/09, UKMC approved protocols that did not include a sufficiently detailed description of the procedures designed to assure that discomfort and pain to animals will be limited to animals to that which is unavoidable. This regulation requires protocols

include a sufficiently detailed description of the procedures designed to assure that_{6 of 241} FOIA 10-549 discomfort and pain to animals will be limited to animals to that which is unavoidable.

9 C.F.R. § 2.31(e)(5) – IACUC.

On 4/14/09, UKMC failed to ensure that all protocols to conduct an activity involving animals contain an appropriate description of the method of euthanasia is to be used. This regulation requires a description of any euthanasia method being used.

9 C.F.R. § 2.32(a) – Personnel qualifications.

On 4/14/09, UKMC failed to ensure all individuals involved in animal care, treatment and use must be qualified to perform their duties and appropriately trained. This regulation requires all personnel involved in the animal care, treatment, and use is qualified to perform their duties. This responsibility shall be fulfilled in part through the provision training and instruction.

9 C.F.R. § 2.33(b)(2) – Adequate Veterinary Care.

On 8/27/08, 3/10/09, 4/14/09, and 6/30/09, UKMC failed to maintain a program of adequate veterinary care that includes the use of appropriate methods to prevent, control, diagnose and treat animals. This regulation requires the use of appropriate methods to prevent, control, diagnose and treat animals.

9 C.F.R. § 2.33(b)(3) – Adequate Veterinary Care.

On 3/10/09 and 4/14/09, UKMC failed to conduct daily observation of all animals to assess their health and well being. This regulation requires daily observations of all animals to assess their health and well being.

9 C.F.R. § 2.33(b)(5) - Adequate Veterinary Care.

On 6/30/09, UKMC failed to provide adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures. This regulation requires adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures.

9 C.F.R. § 2.36(b)(3) – Annual Report.

On 12/18/08, UKMC's Annual Report failed to include two exemptions to the AWA which had been approved by UKMC IACUC Committee. This regulation requires a summary of all exceptions to the standards and regulations be attached to the facility's annual report.

9 C.F.R. § 2.36(b)(7) – Annual Report.

On 3/10/09, UKMC did not report any nonhuman primates on the Annual Report upon which experiments, research, surgery, or tests were conducted involving pain or distress to the animals 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. This regulation requires reporting any nonhuman primates on the Annual Report upon which experiments, research, surgery, or tests were conducted involving pain or distress to the animals for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results or interpretation of the teaching, research, analgesic, or tranquilizing drugs would have adversely affected the procedures, results or interpretation of the teaching, research, experiments, surgery or tests

9 C.F.R. § 2.36(b)(8) – Annual Report.



FOIA 10-54 On 3/10/09, UKMC did not report at least thirty two nonhuman primates on the annual report as being bred, conditioned, or held. This regulation requires reporting the common names and the numbers of animals being bred, conditioned or held for use in teaching, testing, experiments, research or surgery but not yet used for such purposes.

9 C.F.R. § 2.38(b)(1)(iv) – Miscellaneous – Access and inspection of records and property.

On 3/10/09, UKMC failed upon multiple direct requests to accompany the USDA Inspectors into a non-human primate room during the inspection. This regulation requires each research facility to allow access and inspection of facilities as APHIS Officials consider necessary to enforce the provisions of the Act.

9 C.F.R. § 2.38(f)(2)(ii) - Miscellaneous - Handling.

On 4/14/09, UKMC failed to ensure all approved protocols involving the short term withholding of food and water from animals include a description of monitoring procedures. This regulation requires an IACUC approved activity that involves deprivation of food or water include a description of monitored procedures.

9 C.F.R. § 2.38(k)(1) – Miscellaneous – Compliance with standards ad prohibitions.

On 3/10/09, UKMC failed to justify an approved exemption to housing standards to allow one nonhuman primate to be housed in an enclosure that did not meet minimum height requirements. This regulation requires each research facility shall comply with all respects with the regulations set forth in 9 CFR 2 (c) and standards set forth in 9 CFR 3.

9 C.F.R. § 3.25 (a) – Facilities General.

On 3/10/09, UKMC failed to maintain housing facilities for guinea pigs which were structurally sound and in good repair. This standard requires each housing facilities for guinea pigs to develop a program of monitoring and maintenance to ensure that all facilities are structurally sound, and maintained in good repair.

9 C.F.R. § 3.29 (a) - Feeding.

On 8/27/08, UKMC failed to provide wholesome food for guinea pigs. This standard requires each housing facility for guinea pigs provide feed that was free from contamination, wholesome, palatable and sufficient quantity and nutritive value to meet the daily requirements.

9 C.F.R. § 3.56 (c) – Sanitation – Housekeeping.

On 8/27/08 and 3/10/09, UKMC failed to keep rooms housing rabbits free from peeling paint, mold and waste materials. This standard requires each housing facility for rabbits develop and follow a program of monitoring and maintenance to ensure that all premises are kept clean and good repair.

9 C.F.R. § 3.56 (d) - Sanitation - Pest Control.

On 3/10/09, UKMC failed to keep an animal receiving room free from insects on the floor. FOIA 10-549 This standard requires each housing facility housing rabbits must have an effective program for the control of insects, ectoparasites, and avian and mammalian pests.

9 C.F.R. § 3.57 Employees.

On 3/30/09, UKMC failed to keep food/water receptacles clean from tan scaly material. This standard requires each housing facility housing rabbits must ensure that a sufficient number of appropriately trained employees are utilized in order to maintain the prescribed level of husbandry practices.

9 C.F.R. § 3.75 (a) – Housing Facilities, General.

On 8/27/08 and 3/10/09, UKMC failed to maintain rooms housing squirrel monkeys in good repair. This standard requires each housing facility housing nonhuman primates to design, construct and maintain facilities that housed nonhuman primates so that they are structurally sound for the species of nonhuman primates housed in them.

9 C.F.R. § 3.75 (c)(1) Housing Facilities, General – Surfaces.

On 8/27/08 and 3/10/09, UKMC failed to maintain rooms housing squirrel monkeys free from chipping and peeling paint and surfaces which were impervious to moisture. This standard requires housing facilities for nonhuman primates be constructed in a manner that allows them to be readily cleaned and sanitized.

9 C.F.R. § 3.75(c)(1)(i) Housing Facilities, General – Surfaces.

On 3/10/09 and 4/14/09, UKMC failed to maintain rooms housing squirrel monkeys which could be effectively cleaned and sanitized. This standard requires housing facilities housing nonhuman primates to have all surfaces that come in contact with the nonhuman primates free of excessive rust that prevents required cleaning and sanitation.

9 C.F.R. § 3.75 (c)(3) Housing Facilities, General – Surfaces – Cleaning.

On 3/10/09, UKMC failed to maintain rooms housing macaques free of excessive accumulation of fecal material, food residue and drip marks of black to gray material. This standard requires each housing facility housing nonhuman primates to ensure that all hard surfaces which nonhuman primates come into contact with are spot cleaned daily and sanitized.

9 C.F.R. § 3.75 (e) Housing Facilities, General – Storage.

On 3/10/09 4/14/09, UKMC failed to have cleaning supplies, medicines, food and opened food treats stored in an orderly manner. This standard requires each housing facility housing nonhuman primates develop and follow a program of monitoring and maintenance to ensure that supplies of food and bedding are stored in a manner that protects the supplies from spoilage, contamination, and vermin infestation.

9 C.F.R. § 3.75 (f) Housing Facilities, General – Drainage and waste disposal.

On 8/27/08 and 3/10/09 UKMC failed maintain housing facilities of nonhuman primates which were free of standing water on the floors and uncovered trash cans were present. This standard requires housing facilities housing nonhuman primates to provide regular and frequent removal of water and other fluid waste in order to minimize contamination/disease

risk, and drainage is constructed in a manner that minimizes contamination and disease FOIA 10-549 hazard and trash containers must be leak proof and have tightly fitted lids.

9 C.F.R. § 3.76 (c) Indoor Housing Facilities – Lighting.

On 4/14/09 and 6/30/09, UKMC failed to have sufficient lighting to perform inspection and to observe the animals. This standard requires each facility housing nonhuman primates to provide adequate lighting to permit routine inspection and must be uniformly diffused throughout animal facilities to provide sufficient illumination to aid in maintaining good housekeeping practices.

9 C.F.R. § 3.80 (b) (2) (i) Primary Enclosures.

On 3/10/09, UKMC failed to provide adequate space for one adult squirrel monkey which was being housed in an infant incubator. This standard requires each facility housing nonhuman primates to provide minimum space to each nonhuman primate, whether housed individually or with other primates. This minimum space will be determined by the typical weight of the animal of its species.

9 C.F.R. § 3.80 (c) Primary Enclosures.

On 4/14/09, UKMC IACUC approved temporary use of a human infant incubator which did not provide sufficient space for squirrel monkeys while in post-operative recovery. This standard requires the licensee to ensure that all approved innovative enclosures for nonhuman primates provide the nonhuman primates with a sufficient volume of space.

9 C.F.R. § 3.81 Environment enhancement to promote psychological well-being.

On 3/10/09, UKMC failed to develop, document, and follow an appropriate plan for environment enhancement to promote the psychological well-being of nonhuman primates. This standard requires an appropriate plan for environment enhancement adequate to promote the psychological well being of nonhuman primates.

9 C.F.R. § 3.81(a) Environment enhancement to promote psychological well-being – Social grouping.

On 3/10/09, UKMC failed to ensure an environment enhancement plan with specific provisions to address the social needs of nonhuman primates of species known to exist in social groups in nature. This standard requires the environment enhancement plan must include specific provisions to address the social needs of nonhuman primates of species known to exist in social groups in nature.

9 C.F.R. § 3.81 (b) Environment enhancement to promote psychological well-being.

On 3/10/09 and 4/14/09, UKMC failed to provide enrichment reflectors and toys which were in good repair. This standard requires the licensee to develop and follow a program of monitoring and maintenance to ensure that all enrichment items for nonhuman primates are kept in good repair.

9 C.F.R. § 3.81 (c)(2) Environment enhancement to promote psychological well-being.

On 3/10/09 and 4/14/09, UKMC failed to keep twenty eight nonhuman primates from exhibiting abnormal stereotypic behaviors that could be associated with psychological distress. This standard requires the licensee to develop and follow a plan to ensure that those

nonhuman primates that show signs of being in psychological distress thorough behavior or FOIA 10-549 appearance receive special considerations with regard to enhancement of their environment.

9 C.F.R. § 3.81 (c)(4) Environment enhancement to promote psychological well-being.

On 3/10/09, UKMC housed seven macaques with no visual contact with other nonhuman primates. This standard requires the licensee ensure a facility plan for environment enhancement is followed and documented for individually housed nonhuman primates.

9 C.F.R. § 3.81 (e)(2) Environment enhancement to promote psychological well-being.

On 3/10/09, UKMC IACUC failed to develop and follow a plan to ensure nonhuman primates showing signs of psychological distress were evaluated. This standard requires the IACUC must review at appropriate intervals the exemption of an individual nonhuman primate from participation of environment enhancement.

9 C.F.R. § 3.82 (a) Feeding,

On 8/27/08 and 3/10/09, UKMC failed to provide wholesome food for nonhuman primates as food items were past their expiration or best by dates. This standard requires the licensee to develop a program to ensure that all feed is free from contamination, wholesome, palatable, and of sufficient quantity and nutritive value.

9 C.F.R. § 3.84 (b)(3) Cleaning, Sanitization, Housekeeping, and Pest Control

On 3/10/09, UKMC failed to sanitize nonhuman primate enclosures with required temperatures of at least 180 degrees on at least three dates. This standard requires all hard surfaces of primary enclosures housing nonhuman primates be cleaned and sanitized by live steam or washing with at least 180 degree hot water.

9 C.F.R. § 3.84 (c) Cleaning, Sanitization, Housekeeping, and Pest Control

On 3/10/09, UKMC failed to have areas housing nonhuman primates free of towels, clothing and other materials which inhibited adequate husbandry practices. This standard requires the licensee to ensure all premises are kept clean and in good repair in order to protect the nonhuman primates from injury and facilitate the husbandry practices.

9 C.F.R. § 3.84 (d) Cleaning, Sanitization, Housekeeping, and Pest Control

On 3/10/09, UKMC had a box style rodent trap that was located on the shelf of the television cart rather than on the floor. This standard requires the licensee to have an effective program for control of insects and external parasites.

9 C.F.R. § 3.85 Employees

On 3/10/09, UKMC failed to ensure employees were adequately trained in husbandry practices and the care and handling of nonhuman primates. This standard requires the employees who provide husbandry, care, or handle nonhuman primates must be trained and supervised by an individual who has the knowledge, background, and experience in proper husbandry and care of nonhuman primates.

9 C.F.R. § 3.125 (c) Facilities, General – Storage

On 3/10/09 and 4/14/09, UKMC failed to have hay and clean bedding stored in a manner which protected the bedding from deterioration and/or contamination. This standard requires the licensee to ensure all supplies of food and bedding are stored in facilities which adequately protect such supplies against deterioration, molding, or contamination by vermin.



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FOIA 10-549 C.F.R. § 3.131 (b) Sanitation

On 3/10/09, UKMC failed to have the cagewash capable of reaching temperatures to ensure adequate sanitation of surfaces. This standard requires the licensee to ensure that all cages are effectively cleaned and sanitized.

9 C.F.R. § 3.131 (c) Sanitation – Housekeeping

On 3/10/09, UKMC had accumulations of discarded construction materials in a room used to store bedding for gerbils which inhibited adequate cleaning and sanitation. This standard requires the licensee to keep all premises clean and in good repair in order to protect the animals from injury and to facilitate the prescribed husbandry practices.

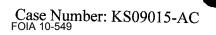
9 C.F.R. § 3.131 (d) Sanitation – Pest Control,

On 3/10/09, UKMC failed have an effective program for the control rodents. This standard requires the licensee to provide an effective program for the control of insects, ectoparasites, and avian and mammalian pests.

9 C.F.R. § 3.132 Employees

On 3/10/09, UKMC failed to have a sufficient number of adequately trained employees to maintain the professionally acceptable level of husbandry practices. This standard requires a sufficient number of adequately trained employees shall be utilized to maintain the professionally acceptable level of husbandry practices.

These findings indicate that the evidence does not support a violation of the following section(s): N/A





Date: 02/198/df041

MITIGATING AND/OR AGGRAVATING FACTORS

N/A

ADDITIONAL INFORMATION

APHIS form 7023 UKMC Annual Report of Research Facility dated 11/30/09 (Exhibit 116).

Case Number: KS09015-AC

Date: 02/18/dr041

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Case Number: KS09015-AC FOIA 10-549

Date: 02/18/10

CASE REPORT DISTRIBUTION (cc)

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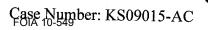
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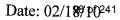


Exhibit #	Description	Date	Total Pages
Exhibit 1	A copy of Registration letter and License Certificate with license number 48 R-0003	04/2707	2
Exhibit 2	A copy of Annual Report of Research	04/17/09	1
Exhibit 3	A copy of Division of the University of Kansas Center for Research	01/12/10	3
Exhibit 4	A copy of University of Kansas Center for Research is registered with the Kansas Secretary of State	12/12/08	3
Exhibit 5	A copy of Request for investigation	04/14/09	2
Exhibit 6	A copy of USDA inspection Report	08/28/08	5
Exhibit 7	A copy of Institutional Animal Care and Use Facility Review	12/18/07	27
Exhibit 8	A copy of Institutional Animal Care and Use Facility Review	06/17/09	27
Exhibit 9	Copies of photographs taken by Dr. Ziegerer	08/27/08	7
Exhibit 10	Copies of photographs taken by Dr. Ziegerer	08/27/08	3
Exhibit 11	Copies of photographs taken by Dr. Ziegerer	08/27/08	3
Exhibit 12	Copies of photographs taken by Dr. Ziegerer	08/27/08	5
Exhibit 13	A copy of USDA inspection Report	12/18/08	2
Exhibit 14	A copy of University of Kansas Center for Research is registered with the Kansas Secretary of State	11/12/08	1
Exhibit 15	A copy of Institutional Animal Care and Use Committee Minutes	05/20/08	10
Exhibit 16	A copy of USDA inspection Report	03/10/09	29
Exhibit 17	A copy of Institutional Animal Care and Use Committee Minutes	10/16/07	11
Exhibit 18	A copy of Institutional Animal Care and Use Committee Minutes	11/20/07	12
Exhibit 19	A copy of Animal Care and Use Proposal 2007- 1688	10/03/07	27

	All redactions on this page are pursuant to (b)(6) & (b)(7)(c).		
Exhibit 20 FOIA 10-549	Copies of Laboratory Animal record # 1911	06/05/07, 06/06/07and 07/23/07,	8 99 of 241
Exhibit 21	Questionnaire answered by Dr.	12/11/09	8
Exhibit 22	A copy of Institutional Animal Care and Use Committee Minutes	03/24/08	10
Exhibit 23	A copy of Institutional Animal Care and Use Committee Minutes	04/14/08	23
Exhibit 24	A copy of Institutional Animal Care and Use Committee Minutes	05/20/08	10
Exhibit 25	A copy of Institutional Animal Care and Use Committee Minutes	06/17/08	8
Exhibit 26	A copy of Institutional Animal Care and Use Committee Minutes	07/15/08	6
Exhibit 27	A copy of Institutional Animal Care and Use Committee Minutes	08/19/08	11
Exhibit 28	A copy of Animal Care and Use Proposal 2007- 1686	10/03/07	18
Exhibit 29	Affidavit obtained from Dr. Katheryn Ziegerer	01/21/10	14
Exhibit 30	Questionnaire answered by	12/11/09	3
Exhibit 31	Copies of photographs taken by Tanya Tims SVMO	03/10/09	87
Exhibit 32	A copy of daily observation of animals Husbandry Room Checklists	2/20/09	6
Exhibit 33	A copy of Annual Report of Research	11/12/08	1
Exhibit 34	A copy of Amended Annual Report of Research	04/03/09	3
Exhibit 35	A copy of Amended Annual Report of Research	01/08/09	1
Exhibit 36	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	2
Exhibit 37	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	11
Exhibit 38	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	31

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Exhibit 39 FOIA 10-549	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	13100 of 241
Exhibit 40	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	8
Exhibit 41	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	18
Exhibit 42	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	50
Exhibit 43	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	7
Exhibit 44	A copy of photograph taken by Tanya Tims, SVMO	03/10/09	1
Exhibit 45	A copy of SOP PROG 8	N/A	5
Exhibit 46	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	15
Exhibit 47	A copy of Institutional Animal Care and Use Committee Minutes	09/16/08	9
Exhibit 48	A copy of photograph taken by Tanya Tims, SVMO	03/10/09	1
Exhibit 49	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	3
Exhibit 50	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	8
Exhibit 51	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	2
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Exhibit 53	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	4
Exhibit 54	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	3
Exhibit 55	Copies of photographs taken by Tanya Tims, SVMO	03/10/09	15

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Exhibit 56	A copy of USDA inspection Report	04/14/09	17
Exhibit 57	A copy of Animal Care and Use Proposal 2008- 1735	05/08/08	37
Exhibit 58	A copy of Animal Care and Use Proposal 2007- 1703	15/05/07	14
Exhibit 59	A copy of Animal Care and Use Proposal 2007- 1680	09/04/07	18
Exhibit 60	Questionnaire answered by	12/11/09	14
Exhibit 61	Questionnaire answered by	12/11/09	6
Exhibit 62	Questionnaire answered by	12/11/09	9
Exhibit 63	Copies of LAR Training Record	12/12/06	5
Exhibit 64	Copies of Lab Animal Records B5-AL11 and B4- 2A0 and B2-4A4 and A5-3A5 and A2-5A9 and C1-57Z and C2-5A	12/11/07	7
Exhibit 65	A copy of SOP PROG 5 Personnel Training	3/09	5
Exhibit 66	A copy of Principal Investigator Training Record	03/02/07	19
Exhibit 67	Copies of photographs taken by Ruth Bakker, VMO	04/14/09	18
Exhibit 68	Copies of Laboratory Animal Record for #99R1027	10/14/08 and 12/07/08	5
Exhibit 69	Copies of Animal Records for animal OAO	10/07/08, 10/15/08and 10/16/08	4
Exhibit 70	Copies of Emails with concerns for animal 0A0	10/08 and 1016/08	2
Exhibit 71	Copy of Primate Master record for 0A0	12/21/07	1
Exhibit 72	Copies of Laboratory Animal Record for 3A0	10/07/08, 10/09/08 and 10/10/08	3
Exhibit 73	Copies of Emails with concerns for animal 3A0	10/09/08 and 10/10/08	2
Exhibit 74	A copy of Animal record for animal 3A0	10/20/08	1
Exhibit 75	Primate Mater Record for animal 99R1027	01/01/07	1

Exhibit 76 FOIA 10-549	Primate Mater Record for animal 674	11/04	1 102 of 241
Exhibit 77	Primate Mater Record for animal 622	5/18/09	1
Exhibit 78	Primate Mater Record for animal 702	05/15/09	1
Exhibit 79	Primate Mater Record for animal 668	5/15/09	1
Exhibit 80	Primate Mater Record for animal 695	5/20/09	1
Exhibit 81	Copies of photographs taken by Ruth Bakker, VMO	04/14/09	2
Exhibit 82	Copies of photographs taken by Ruth Bakker, VMO	04/14/09	2
Exhibit 83	Copies of photographs taken by Ruth Bakker, VMO	04/14/09	3
Exhibit 84	Copies of photographs taken by Ruth Bakker, VMO	04/14/09	2
Exhibit 85	A copy of SOP HUSB 1 Food, Water and Bedding Management	04/09	11
Exhibit 86	Copies of photographs taken by Ruth Bakker, VMO	04/14/09	2
Exhibit 87	Copies of photographs taken by Ruth Bakker, VMO	04/14/09	3
Exhibit 88	A copy of SOP Prog 8 Promotion of Psychological Well Being of Non-human Primates	N/A	14
Exhibit 89	Copies of photographs taken by Ruth Bakker, VMO	04/14/09	26
Exhibit 90	Copy of video taken by Ruth Bakker, VMO	04/14/09	1
Exhibit 91	Copies of photographs taken by Ruth Bakker, VMO	04/14/09	2
Exhibit 92	A copy of USDA Inspection Report	06/30/09	5
Exhibit 93	A copy of Animal Care and Use Proposal 2007- 1619	01/05	12
Exhibit 94	A copy of Animal Care and Use Proposal 2006- 1581	01/05	14

All redactions on this page are pursuant to (b)(6) & (b)(7)(c).			
Exhibit 95 FOIA 10-549	Questionnaire answered by Culley, Veterinarian	12/11/09	3 103 of 241
Exhibit 96	Questionnaire answered by	12/11/09	3
Exhibit 97	A copy of Animal Care and Use Proposal 2009- 1796	04/13/09	38
Exhibit 98	Copies of MRI Scan Procedures	06/22/09	9
Exhibit 99	A copy of Treatment Record for animal AV82	05/20/09	1
Exhibit 100	A copy of Treatment Record for animal 5A9	06/19/09	1
Exhibit 101	A copy of Treatment Record for animal 5A3	06/19/09	1
Exhibit 102	A copy of Treatment Record for animal 702	6/19/09	1
Exhibit 103	A copy of Treatment Record for animal 3A1	06/19/09	1
Exhibit 104	A copy of Treatment Record for animal 99R1837	05/29/09	1
Exhibit 105	Laboratory Animal Record for 11F	05/06/09	2
Exhibit 106	Affidavit obtained from Dr. Tanya Tims	07/25/09	1
Exhibit 107	Affidavit obtained from Dr. Jami Niemann	08/05/09	1
Exhibit 108	Affidavit obtained from Dr. Ruth Bakker	11/30/09	2
Exhibit 109	Questionnaire answered by DVM	12/11/09	27
Exhibit 110	Questionnaire answered by	12/11/09	108
Exhibit 111	Questionnaire answered by	12/11/09	37
Exhibit 112	E mails from Thomas Field (UKMC Interim Associate Vice Chancellor for Compliance)	10/22/09 7 10/25/09	4
Exhibit 113	Email from Thomas Field (UKMC Interim Associate Vice Chancellor for Compliance)	12/11/09	1
Exhibit 114	Attachments received from KU Med Center	12/14/09	221
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Exhibit 116	A copy of Annual Report of Research	11/30/09	10
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COPY

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 April 27, 2007 Customer No: 1460 Certificate No: 48-R-0003 Anniversary Date: 05/04/2010 RE: ACKNOWLEDGEMENT OF UPDATE

Dear Registrant:

3901 Rainbow Blvd

University Of Ks Med Ctr

Kansas City, KS 66160

1040 Wescoe Pavilion - Ms 2014

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 you 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 970-494-7472 if you have any questions regarding this letter or the Animal Welfare Act.

Sincerely,

Low Thitilum

Robert M. Gibbens Regional Director - Animal Care Western Region

cc: Tanya Tims, V.M.O. Enclosures



FOIA 10-549	Programs Animal and Plant Health Inspection Service Animal Care	United States Department of Agriculture Marketing and	NSDA NSDA
Deputy Administrator	Animal Welfare Act(7 U.S.C. 2131 et seq.)Certificate No.Certificate No.Customer No.	This is to certify that UNIVERSITY OF KS MED CTR is a registered under the	EXPIRATION DATE: MAY 4, 2010
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UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE 1. REGISTRATION N 48-R-0003 ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT) 1. HEADQUARTERS I include Zip Code) 3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or expo sheets if necessary.) See Attached Listing C. Number of animals Covered By The Animal Welfare Regulations B. Number of auimals being bred, conditioned, or heid for use in seperiments, research, or surgery but not yet used for such purposes. C. Number of animals upon which teaching, research, experiments, or teast were conducted involving no pain, distress, or tranquilizing drugs were purposes. D. Number of animals upon which experiments, research, or surgery but not yet use of pain- reference drug D. Number of animals upon which experiments, or tests were oracuted involving areasthetic, analgesic, or tranquilizing drugs were areasthetic, analgesic, or tranquilizing drugs were areasthetic, analgesic, or	ee reverse side of formation. N NO. CUSTOMER NO. 1460 RS RESEARCH FACILITY (Name and Address, as registered with USL OMB NO. 0579-0038 UNIVERSITY OF KS MED CTR 3901 RAINBOW BLVD 1040 WESCOE PAVILION - MS 2014 KANSAS CITY, KS 66160 (913) 588-7015 Experimentation, or held for these purposes. Attach additional
This 'sport is required by law (7 USC 2143). Failure to the 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. Sectio	ee reverse side for Iditional information. Interagency Report Control M 0180-DOA-AN N NO. CUSTOMER NO. 1460 FORM APPROVED OMB NO. 0579-0038 RS RESEARCH FACILITY (Name and Address, as registered with USL 000000000000000000000000000000000000
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and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility. Each principal investigator has considered attempting to a surgery or experimentation were followed by this research facility.	hetic, analgesic, and tranquilizing drugs prior to during
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APHIS FORM 7023 (AUG 91)

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(Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

APR 2 3 2009

About the University of Kansas Medical Center

The University of Kansas Medical Center is a campus of the University of Kansas and offers educational programs through its Schools of Allied Health, Medicine, Nursing, and Graduate Studies. The campus is comprised of academic units operating alongside The University of Kansas Hospital, which provides opportunities for clinical experience and residency positions.

Mission Statement

The University of Kansas Medical Center, an integral and unique component of the University of Kansas and the Kansas Board of Regents system, is composed of the School of Medicine, located in Kansas City and Wichita, the School of Nursing, the School of Allied Health, the University of Kansas Hospital in Kansas City, and a Graduate School. The KU Medical Center is a complex institution whose basic functions include research, education, patient care, and community service involving multiple constituencies at state and national levels. The following paragraphs chart the KU Medical Center's course and serve as a framework for assessing programs, setting goals, developing initiatives and evaluating progress.

The University of Kansas Medical Center is a major research institution primarily serving the State of Kansas as well as the nation, and the world, and assumes leadership in the discovery of new knowledge and the development of programs in research, education, and patient care. The KU Medical Center recognizes the importance of meeting the wide range of health care needs in Kansas – from the critical need for primary care in rural and other underserved areas of the state, to the urgent need for highly specialized knowledge to provide the latest preventive and treatment techniques available. As the major resources in the Kansas Board of Regents system for preparing health care professionals, the programs of the KU Medical Center must be comprehensive and maintain the high scholarship and academic excellence on which the reputation of the University is based. Our mission is to create an environment for:

Instruction. The KU Medical Center educates health care professionals to primarily serve the needs of Kansas as well as the region and the nation. High quality educational experiences are offered to a diverse student population through a full range of undergraduate, graduate, professional, postdoctoral and continuing education programs.

Research. The KU Medical Center maintains nationally and internationally recognized research programs to advance the health sciences. Health related research flourishes in a setting that includes strong basic and applied investigations of life processes, inquiries into the normal functions of the human body and mechanisms of disease processes, and model health care programs for the prevention of disease and the maintenance of health and quality of life.

Service. The KU Medical Center provides high quality patient-centered health care and health related services. The University of Kansas Medical Center will be the standard bearer in the development and implementation of model programs that provide the greatest possible diversity of proven health care services for the



Page 1 of 2

Meet Barbara Atkinson, MD Executive Vice Chancellor

Related Info

Advancement Board

Chancellor of the University of Kansas

Executive Vice Chancellor, Medical Center

Kansas Board of Regents

KUMC Tours

KU Medical Center at a Glance (a statistical report)

Local area information links

Maps, directions and frequently called phone numbers

Organizational Charts

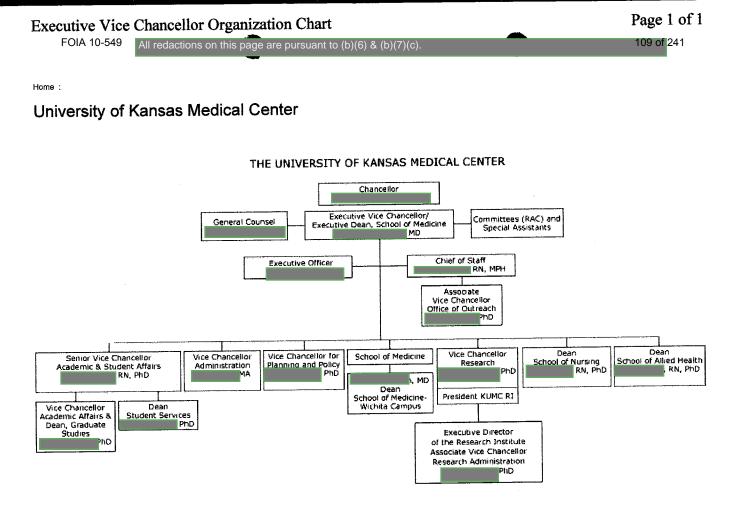


http://www.kumc.edu/Pulse/aboutkumc.html

citizens of Kansas, the region and the nation. (5-28-89; 12-17-92).

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Last updated: Wednesday, January 6, 2010

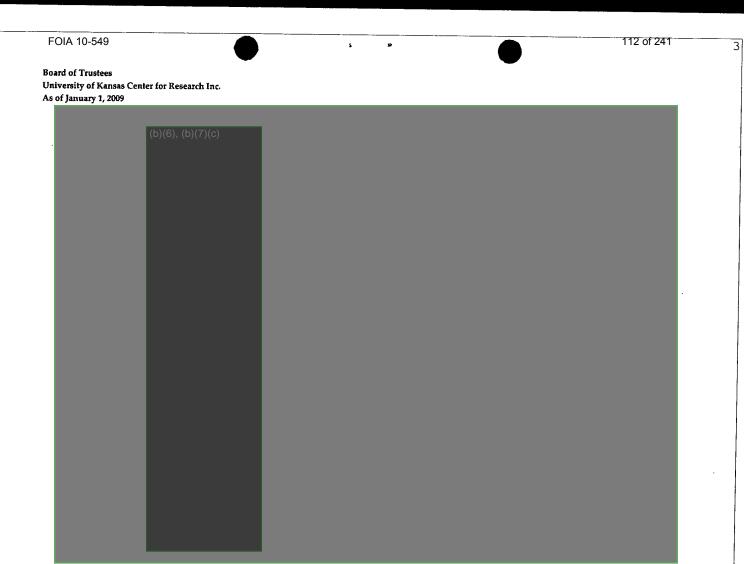
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Contact Information				KANSAS SECRET		
Kansas Secretary of State Ron Thornburgh		Not-f	for-Profit	t Corporation A	nnual Repo	ort INP
Memorial Hall, 1st Floor						50
120 S.W. 10th Avenue						
Topeka, KS 66612-1594				eted and the required t		
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kssos@kssos.org	compt	ecing this do	cument.			
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(Name must match the name		Secretary of St	tate)	***	A SB FILED B	Y KS 505
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Please answer question 9 if the corporation	issues stock Answer a	uestion 10 if the componation inst	ead has members
(Must answer all lines with a numeric value			
9. Total number of shares of capital stock iss			
y, rous number of shares of capital score is			
0. Total number of members: 36			
_			
1. Federal Employer ID Number (FEIN):	48-0680117		
2. Does this corporation hold more than 50%	equity ownership in any	y other business entity that is <u>file</u>	d with the Kansas Secretary of
State?			
YES Complete the lines below.	NO <u>X</u> Skip te	o question 13.	
lease provide the name of the business(es) exit			ude the Business Entity ID
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December, 2008





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April 14, 2009

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 Tim Fordahl Western Regional Director Investigative & Enforcement Services

Request for Investigation of Alleged Violations Regarding the Animal Welfare Act, Regulations, and/or Standards

Please initiate an investigation on the following individual:

NAME:	University of Kansas Medical Center
ADDRESS:	3901 Rainbow Blvd
	1040 Wescoe Pavilion- MS 2014
CITY:	Kansas City, KS 66160
LIC / REG. #:	48-R-0003 / customer #1460

ADDITIONAL INFORMATION:

Repeated failure to provide adequate veterinary care, and to properly clean and maintain facilities. The facility has numerous IACUC oversight violations, and numerous violations that affect the psychological well-being of non-Human Primates at the facility. In addition, the facility does not have an adequate number and/or properly trained personnel to carry out the level of care and husbandry practices required by the Animal Welfare regulations. Due to the number and seriousness of these violations, and the potential negative impact on animal welfare, an investigation is requested. Animal Care is expecting to receive an appeal to the March 10, 2009 inspection report.

If further information is needed, please let me know.

durthe Lilit

Robert M. Gibbens Director, Western Region USDA, APHIS, Animal Care





Memorandum

TO :	Wendy Gonzales
	Area Manager

FROM: Timothy Fordahl Western Regional Director

DATE: April 14, 2009

SUBJECT: Request for Investigation

Please find enclosed a request for investigation from Robert Gibbens, Director of Animal Care in Fort Collins, CO, regarding alleged violations involving:

University of Kansas Medical Center 3901 Rainbow Blvd 1040 Wescoe Pavilion-MS2014 Kansas City, K\$ 66160 Lic/Cust#: 43-R-0003/customer#1460

Re: Repeated failure to provide adequate veterinary care, and to properly clean and maintain facilities.

Please assign this investigation accordingly. Investigators are directed to:

- Open an investigation in the IES Tracking System within (five) 5 days of receipt of this request
- E-mail the case number to your PSA, Area Manager, (b)(6), (b)(7)(c) (b)(6), (b)(7)(c) rithin 10 working days
- Complete this investigation within the required 100 day time frame outlined in the IES Training Manual

If a complication arises, or, if you have any questions or concerns regarding this request, notify your Area Manager immediately.

TO BE COMPLETED BY FIELD INVESTIGATOR:

Case Number Assigned: $\underline{KS09015}$

Timothy Fordahl Regional Director Western Regional Office Investigative and Enforcement Services







United States Department of Agriculture Animal and Plant Health Inspection Service

(INSPECTION REPORT)

^{KZIEGERER} 115 of 241 **1460 cust_id** 338118 insp_id 4135 site id

UNIVERSITY OF KANSAS MEDICAL CENTER Customer ID: 1460 Certificate: 48-R-0003

Site: 001

UNIVERSITY OF KS MED CTR

Inspection Type: ROUTINE INSPECTION Date: AUG-27-2008

KANSAS CITY, KS 66160

1040 WESCOE PAVILION - MS 2014

2.31 (c)(3)

3901 RAINBOW BLVD

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(c) IACUC Functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall: (3) Prepare reports of its evaluations conducted as required by paragraphs (c)(1) and (2) of this section, and submit the reports to the Institutional Official of the research facility; Provided, however, That the IACUC may determine the best means of conducting evaluations of the research facility's programs and facilities; and Provided, further, That no Committee member wishing to participate in any evaluation conducted under this subpart may be excluded. The IACUC may use subcommittees composed of at least two Committee members and may invite ad hoc consultants to assist in conducting the evaluations, however, the IACUC remains responsible for the evaluations and reports as required by the Act and regulations. The reports shall be reviewed and signed by a majority of the IACUC members and must include any minority views. The reports shall be updated at least once every six months upon completion of the required semiannual evaluations and shall be maintained by the research facility and made available to APHIS and to officials of funding Federal agencies for inspection and copying upon request. The reports must contain a description of the nature and extent of the research facility's adherence to this subchapter, must identify specifically any departures from the provisions of title 9, chapter I, subchapter A -- Animal Welfare, and must state the reasons for each departure. 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. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency. Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within:15 business days by the IACUC, through the Institutional Official, to APHIS and any Federal agency funding that activity;

The reports pertaining to the Fall 2007 and Spring 2008 program and facility reviews conducted by the IACUC were examined by the inspectors. Although minor deficiencies were identified by the committee, a specific plan and schedule for correction with dates was not included in the reports. The reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency, in order to ensure that all deficiencies are addressed in a timely manner to protect the health and welfare of the animals. The registrant must ensure that all future facility and program review reports contain a specific plan and schedule with dates plan and schedule with dates for correcting each deficiency identified.

Page 1 of 5

TO BE CORRECTED on all future program and facility review reports.

2.33 (b)(2) ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Prepared By:

KATHERYN ZIEGERER, V.M.O., JUSDA, APHIS, Animal Care

VETERINARY MEDICAL OFFICER, Inspector ID: 5052

Received By:

Title:

Title:

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

Date: AUG-28-2008

Date: AUG-28-2008



2008

SFP - 2





United States Department of Agriculture Animal and Plant Health Inspection Service

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(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;

During the inspection of two laboratory areas, expired medications were observed including: 0.9% sodium chloride for drug dilution (expired Nov 07), epinephrine (exp 6-08), Dexamethasone (exp 4-08), xylazine (exp 6-08), Aminax ointment (exp Apr 07), Children's Advil (exp 08/03), Tylanol Infant Drops (exp 05/07), Motrin Jr. Strength (exp 04/06), atropine ophthalmic (exp 12/81), injectable penicillin (exp Mar 05), Fura Septin soluble dressing (exp 1995), lidocaine injection (exp 1Aug05), and Children's Apar Elixir (exp 10/04). Expired medications may no longer work as expected and could harm the animals. The program of veterinary care must include the use of appropriate methods to treat diseases in order to protect the health of the animals. The registrant must develop a program of monitoring and maintenance to ensure that all medications utilized for regulated species are within date.

TO BE CORRECTED BY: September 8, 2008

3.29 (a)

FEEDING.

(a) Guinea pigs and hamsters shall be fed each day except as otherwise might be required to provide adequate veterinary care. The food shall be free from contamination, wholesome, palatable and of sufficient quantity and nutritive value to meet the normal daily requirements for the condition and size of the guinea pig or hamster.

In Room 5007C, housing 9 Guinea pigs, the feed container being utilized was marked "Expiration date 7/22/08." Food that is used past its expiration date may no longer be wholesome, palatable, or meet the nutritional needs of the animals. All feed must be wholesome, palatable, and of sufficient nutritive value to maintain the health of the animals. The registrant must develop a program of monitoring and maintenance to ensure that all feed is free from contamination, wholesome, palatable, and of sufficient the normal daily requirements of the animals.

TO BE CORRECTED BY: August 29, 2008

3.56 (c) SANITATION.

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

In Room 5018, housing 15 rabbits, the ceiling had several areas of cracked, pealing paint. Additionally, a large area of the ceiling immediately above the animals and around a canister was covered with a black, spotted substance with a mold-like appearance. The black substance was also present on the wall in that area. All buildings used to house animals must be kept clean and in good repair in order to facilitate the required cleaning and sanitization and to protect the health and welfare of the animals. The registrant must clean and/or repair the aforementioned areas and develop a program of monitoring and maintenance to ensure that all premises are kept clean and in good repair at all times.

Prepared By:	Blathe happing NIII, 1/110	SEP	· · · · 2008
Ргерагео Бу:	KATHERYN ZIEGEBER, V.M.O., USDA, APHIS, Animal Care	Date:	
Title:	VETERINARY MEDICAL OFFICER, Inspector ID: 5052	AUG-28-2008	
Received By:	(b)(6), (b)(7)(c)		
		Date:	
Title:		AUG-28-2008	
	Page 2 of 5		



United States Department of Agriculture Animal and Plant Health Inspection Service

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TO BE CORRECTED BY: October 15, 2008

3.75 (a)

3.75 (c)(1)

3.75 (f)

HOUSING FACILITIES, GENERAL.

(a) Structure: construction. 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, and they must protect the animals from injury, contain the animals securely, and restrict other animals from entering.

Room 5009, housing 19 squirrel monkeys, had several areas on the ceiling with cracked and pealing paint. All buildings used to house animals must be kept clean and in good repair in order to facilitate the required cleaning and sanitization and to protect the health and welfare of the animals. The registrant must repair the aforementioned areas and develop a program of monitoring and maintenance to ensure that all premises are kept clean and in good repair at all times.

TO BE CORRECTED BY: October 15, 2008

(c) Surfaces

(1) General requirements. The surfaces of housing facilities -- including perches, shelves, swings, boxes, houses, dens, and other furniture-type fixtures or objects within the facility -- must be constructed in a manner and made of materials that allow them to be readily cleaned and sanitized, or removed or replaced when worn or soiled. Furniture-type fixtures or objects must be sturdily constructed and must be strong enough to provide for the safe activity and welfare of nonhuman primates. Floors may be made of dirt, absorbent bedding, sand, gravel, grass, or other similar material that can be readily cleaned, or can be removed or replaced whenever cleaning does not eliminate odors, diseases, pests, insects, or vermin.

A wall in a room housing 15 squirrel monkeys had an irregularly shaped area of wall damage that was approximately 12 by 8 inches in size. The wall was damaged to the point that the underlying drywall material that is not impervious to moisture and can not be effectively cleaned and sanitized was exposed. All surfaces within housing facilities must be constructed in a manner that allows them to be readily cleaned and sanitized in order to protect the health of the animals. The registrant must repair the aforementioned area and develop a program of monitoring and maintenance to ensure that all surfaces of housing facilities are constructed in a manner that allows them to be readily cleaned to be readily cleaned and sanitized at all times.

TO BE CORRECTED BY: September 15, 2008

(f) Drainage and waste disposal. Housing facility operators must provide for regular and frequent collection, removal, and disposal of animal and food wastes, bedding, dead animals, debris, garbage, water, and any other fluids and wastes, in a manner that minimizes contamination and disease risk. Housing facilities must be equipped with disposal facilities and drainage systems that are constructed and operated so that animal wastes and water are rapidly eliminated and the animals stay dry. Disposal and drainage systems must minimize vermin and pest infestation, insects, odors, and disease hazards. All drains must be properly constructed, installed, and maintained. If closed drainage systems are used, they must be equipped with traps and prevent the backflow of gases and the backup of sewage onto the floor. If the facility uses sump ponds, settlement ponds, or other similar systems for drainage and animal waste disposal, the system must be located far

SFP - 2 2008 egeres, DVM, VMO Prepared By: KATHERYN ZIEGERER, V.M.O., USDA, APHIS, Animal Care Date: Title: VETERINARY MEDICAL QFFICER, Inspector ID: 5052 AUG-28-2008 **Received By:** Date: AUG-28-2008 Title: ASSOCIATE DIRECTOR

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United States Department of Agriculture Animal and Plant Health Inspection Service

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enough away from the animal area of the housing facility to prevent odors, diseases, insects, pests, and vermin infestation. If drip or constant flow watering devices are used to provide water to the animals, excess water must be rapidly drained out of the animal areas by gutters or pipes so that the animals stay dry. Standing puddles of water in animal areas must be mopped up or drained so that the animals remain dry. Trash containers in housing facilities and in food storage and food preparation areas must be leakproof and must have tightly fitted lids on them at all times. Dead animals, animal parts, and animal waste must not be kept in food storage or food preparation areas, food freezers, food refrigerators, and animal areas.

Areas of standing water were present on the floors of three rooms containing a total of 28 non-human primates. No active cleaning was being conducted in these rooms at the time of the inspection. Facilities must provide for the regular and frequent removal of water and other fluid wastes in order to minimize contamination/disease risk and to protect the health of the animals. The registrant must ensure that waste water and other standing water in animal areas are regularly and frequently removed.

TO BE CORRECTED BY: August 29, 2008

In a non-human primate lab, a refrigerator was present that was storing necropsy/tissue samples and medications including wound dressings, ophthalmic medications, and injectable medications. The refrigerator had a brown, liquid substance present on some of its surfaces. Storage of necropsy and tissue samples in the same refrigerator as animal medications could result in contamination of the products and negatively impact the health and welfare of the animals. The registrant must ensure that dead animals, animal parts, and animal waste are not kept in food storage/food preparation areas, food freezers/refrigerators, or animal areas.

TO BE CORRECTED BY: September 8, 2008

3.82 (a)

FEEDING.

Title:

(a) The diet for nonhuman primates must be appropriate for the species, size, age, and condition of the animal, and for the conditions in which the nonhuman primate is maintained, according to generally accepted professional and husbandry practices and nutritional standards. The food must be clean, wholesome, and palatable to the animals. It must be of sufficient quantity and have sufficient nutritive value to maintain a healthful condition and weight range of the animal and to meet its normal daily nutritional requirements.

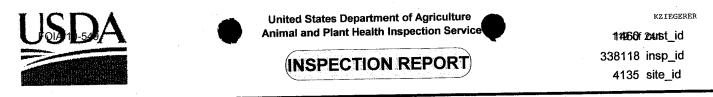
During the course of the inspections, enrichment food items for non-human primates in the animal facilities or laboratory areas were observed that were past their expiration or "best by" dates. Items observed included pineapple chunks (exp 6-23-08), raisins (exp 01-08), "Ritz bits" (exp 11-13-07), peanuts (exp 4-10-08), dried cranberries (exp 5-14-08), Jet-puffed fun marshmallows (exp 5-23-08), raisins (best if used by Jan 28, 06), raisins (best if used by Jun 01, 05), prunes (best before 240807), Sunflower Nuts (Freshest if used by 062907), and raisins (best by Feb 13, 04). Food that is used past its expiration date may no longer be wholesome, palatable, or meet the nutritional needs of the animals. All feed must be wholesome, palatable, and of sufficient nutritive value to maintain the health of the animals. The registrant must develop a program of monitoring and maintenance to ensure that all feed is free from contamination, wholesome, palatable, and of sufficient quantity and nutritive value to meet the normal daily requirements of the animals.

SFP - 9 2008 aeres, Prepared By: KATHERYN ZIEGERER, W.M.O. JUSDA, APHIS, Animal Care Date: VETERINARY MEDICAL OFFICER, Inspector ID: 5052 AUG-28-2008 Title: **Received By:** Date:

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AUG-28-2008



TO BE CORRECTED BY: August 29, 2008

This routine inspection was conducted with Katheryn Ziegerer, VMO, Jami Niemann, VMO, and facility representatives on August 27 and 28, 2008. An exit conference was conducted on August 28, 2008.

Prepared By:

IN, VMO Meri KATHERYN ZIEGEBER, V.M.Ø., USØA, APHIS, Animal Care

Title: Received By:

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

Date: AUG-28-2008

Date: AUG-28-2008

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Title: ASSOCIATE DIRECTOR

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FOIA 10-549



The University of Kansas Medical Center

Institutional Animal Care and Use , PhD, Chair

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MEMORANDUM

То:	, JD, MPH Associate Vice Chancellor for Compliance
From:	Heuvel, Ph.D. Chair, Institutional Animal Care and Use Committee
Subject:	Semi-Annual Evaluation of Program and Facilities Report to the Institutional Official
Date:	December 18, 2007

This memorandum represents the semiannual report of the Institutional Animal Care and Use Committee (IACUC) as required by the PHS Policy on Humane Care and Use of Laboratory Animals and as a condition of this institution's Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW) and USDA Animal Welfare Regulations. These regulations require that the IACUC review the University's animal care and use program and facilities every 6 months and provide a summary of this review to the University's Institutional Official. The IACUC conducted its semiannual evaluation of the institution's animal care and use program during the months of October and November 2007. This review included visits of individual investigator laboratories and assessment of the animal facilities and programs.

Evaluation of Individual Investigator Laboratories

Committee members visited individual laboratories in the months of October and November to inspect their facilities, discuss animal care, adherence to protocols, and educate investigators and staff on compliance issues. Particular emphasis was placed on training; knowledge of the protocol, including review of approved procedures; changes requiring addenda; AVMA approved methods of euthanasia and proper management of scheduled drugs. No major or serious deficiencies or issues of noncompliance were identified. Some minor deficiencies were found including unused out of date drugs in one lab, scheduled drug not stored correctly and/or log not available in one lab, out of date surgical supplies were found in two labs, one surgery room did not have 70% diluted ETOH although is was present in the outer lab, one lab was using halothane outside of a fume hood and one lab needed more detail in surgical records. These issues were resolved the day of or shortly after the day of inspection or are in the process of being corrected. All corrections should be completed by the January IACUC meeting.

Evaluation of the Animal Care and Use Program

A five-member subcommittee reviewed the animal facilities and programs on November 6, 2007, and concluded the overall organization of the program to be in compliance with all



Office of Compliance Animal Research Protection Program MSN 2014, 3901 Rainbow Blvd., 1054 Wescoe, Kansas City, KS 66160 Phone: (913) 588-2416 Fax: (913) 588-1224

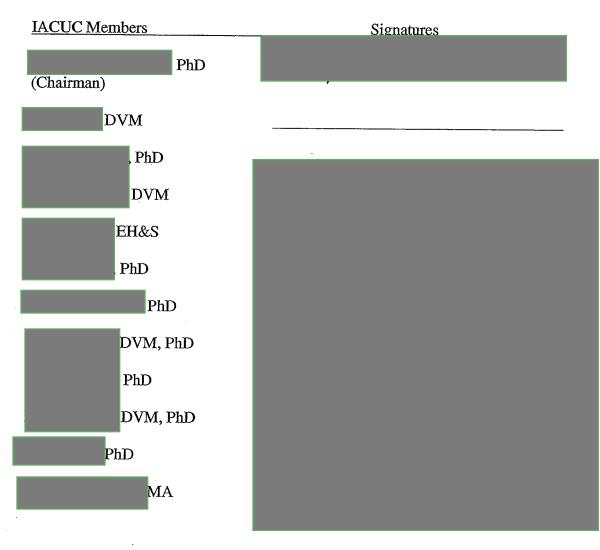
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federal requirements. The committee inspected all animal facilities in Building #30 and Smith, as well as satellite facilities in the Hoglund Brain Imaging Center and Wahl Hall East.

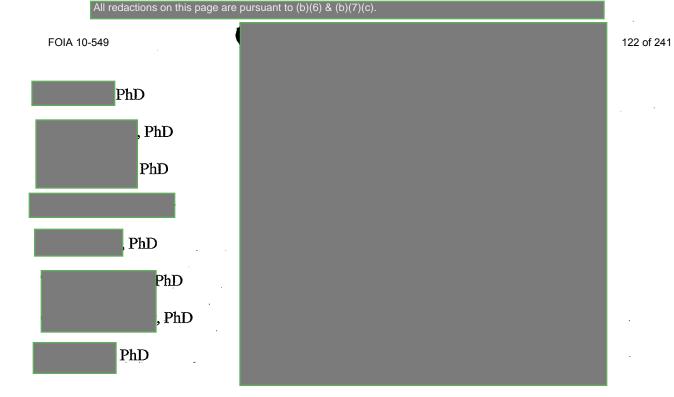
The committee found the general condition of all facilities satisfactory; however, the building regulator in Building #30 was preventing steam from entering the building but a contractor was scheduled to make repairs later the same day. Minimal problems were found other than the condition and operation of the dirty cagewash area in the LAR. These minor issues were out of date drug found in a procedure room in the LAR and Hoglund Brain Imaging Center and the general cleanliness of the behavior core. The cagewash is in need of complete renovation, including the equipment, plumbing, walls, ceilings and floors. The minor issues have all been corrected. Repairs and renovations of the cagewash will be done in conjunction with federally funded replacement of the cagewash equipment this fall. There are animal housing areas with no provision for undisturbed observation of animals because a few rooms do not have windows in them. The LAR management continues to instruct the cagewash staff to use proper ear protection.

Minority Views

There were no minority views from the IACUC committee regarding the semiannual review or report.







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FOIA 10-549

Annual Review: Institutional Polices and Responsibilities

Revised 8/99

Instructions: This form is used in the semi-annual evaluation of institutional polices and responsibilities. Each component is evaluated in the context of the Guide for the Care and Use of Laboratory Animals, the Animal Welfare Act, and the PHS Policy. A component judged compliant is marked in the "A" column. Those with minor deficiencies are marked in the "M" column. Those with significant deficiencies are marked in the "S" column. Minor and significant deficiencies must be detailed by component in the notes section.

Date of Evaluation		
Evaluators Printed Name Signature		<u>į</u>
Criteria	A M.	Տ
1.0 IACUC membership and functions	7	
1.1 Minimum of 5 members, appointed by the institutional official.	5	
1.2 Members include veterinarian, scientist, non-scientist, non-affiliated person	J	
1.3 Responsible for oversight and evaluation of the institution's program		
1.4 Reports to the institutional official	J	
1.5 Conducts semi-annual evaluations of animal care and use program	.)	
1.6 Conducts semi-annual evaluations of animal facilities	C	
1.7 Reviews and investigates concerns about animal care and use at the institution	1	
1.8 Procedures for review, approval and suspension of animal activities	ノ	
1.9 Procedures for review and approval of significant changes to approved activities	2 0	
1.10 Policies for special procedures (restraint, mult surgeries, food/fluid restriction)	د	
2.0 IACUC Records and Reporting Requirements	J I	
2.1Reports to the institutional official (IO)	1	
2.1.1 Reports of semi-annual reviews and facilities inspections to IO	$\overline{\lambda}$	
2.1.2 Includes minority views of IACUC members)	
2.1.3 Describes departures from Guide or PHS Policy and reasons for departure	5	
2.1.4 Distinguish minor and significant deficiencies	1	
2.1.5 Include a plan and schedule for correction of each deficiency	3	
2.2 Reports to Office for Protection from Research Risks (OPRR)		
2.2.1 Annual Report includes minority views of IACUC members	ل 1	
2.2.2 Annual report documents changes; gives dates of semi-annual inspections		
2.2.3 Promptly advises OPRR of serious Guide deviations or Policy non-compliance		
2.2.4 Promptly adivses OPRR of any suspension of activity by the IACUC		



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Criteria	$\langle \rangle$	A	Μ	S
2.3 Reports to the United States Department of Agriculture	<u>X</u>)		
2.3.1 Annual report containing required information		2		
2.3.2 Reporting mechanism in place for IACUC-approved exceptions to regulations	3.1-	,		
2.3.3 Reports within 15 days failure to adhere to timetable of deficiency correction	\mathbf{X}	J		
2.3.4 Reports IACUC-mandated suspension of activity to USDA and any federal		1		
funding agency				
2.3.5 Minutes of IACUC meetings and semi-annual inspections maintained for 3 yr	s	j		
2.3.6 IACUC review documentation maintained for 3 yrs after completion of study	\mathbf{N}	1		
2.3.7 IACUC review of activities involving animals includes all required		5		
information	\leq	<u> </u>		
3.0 Veterinary Care	\leq	\sum		
3.1 Veterinarians with training or experience in lab animal medicine available		Ĵ		
3.2 Veterinarians have access to all animals	\searrow	<u>)</u>		
3.3 Provision for back-up veterinary care	\downarrow	2		
3.4 Availability of guidance in handling, immobilization, sedation, anesthesia,		5		1
analgesia	\uparrow	ر ا		
3.5 Guidance and oversight of surgery programs and post-surgical care	Ľ.)		
3.6 Authority to oversee all aspects of animal care and use	\square	Ĵ		
4.0 Personnel Qualifications and Training		1		
4.1 Institution has established and implemented an effective training program	\rightarrow)		
4.2 Training includes professional/management/supervisory personnel	$\overline{\neg}$	Š		
4.3 Training includes animal care personnel	\neg	<u>,</u>		
4.4 Training includes research investigators, instructors, technicians, trainees,		\		
students	\uparrow	J		
4.5 Training Program Content		3		
4.5.1 Humane practices of animal care (housing, husbandry, handling)	$\overline{\}$	2		
4.5.2 Humane practices of animal use (surgery, anesthesia, analgesia, etc.))		
4.5.3 Alternative methods that minimize number of animals needed)	·	
4.5.4 Research/testing methods that minimize pain or distress		1		
4.5.5 Hazard communication program		5		
5.0 Occupational Health and Safety of Personnel				
5.1 Institutional Program for a Safe and Healthy Workplace		2		
5.1.1 Program is established and implemented	-	~4		
5.1.2 Covers all personnel who work in laboratory animal facilities	\neg	٦		
5.1.2 Program is based on hazard identification and risk assessment	$\overline{\mathbf{x}}$	J	[
5.1.4 Training in specific hazards (zoonoses, pregnancy, un-defined illnesses, etc.)		>		
5.1.5 Personal hygiene procedures and equipment	\downarrow	<u> </u>		
5.1.6 Procedures for storage, use and disposal of hazardous agents	$\overline{}$	-	<u> </u>	
5.1.7 Specific Procedures for personnel protection (shower, change facilities, injury	v			
prevention)		\sim		
5.1.8 MSDS available through the institution	\rightarrow	<u> </u>		<u> </u>
			. <u></u>	



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Criteria	A	M	S
5.2 Program for medical evaluation and Preventative Medicine for Personnel	\mathcal{I}		
5.2.1 Employment evaluation including health history)		
5.2.2 Immunizations as appropriate (rabies, tetnus) plus any tests needed	د		
5.2.3 Zoonosis surveillance as needed	2		
5.2.4 Procedures for reporting and treating injuries (exposure control)	<u>ງ</u>		
5.3 Special Precautions for Personnel Working With Primates			
5.3.1 Tuberculosis screening	Ľ		
5.3.2 Exposure control program for bites, scratches, needle sticks, etc.	<u></u>		
5.3.3 Education regarding Cercopithecine herpesvirus 1 (Herpes B)	·		

NOTATIONS	S: Please indicate the item number and detail any minor or significant deficiencies noted.			
<u> </u>				



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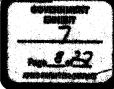
Revised 8/99

Instructions: This form is used in the semi-annual evaluation of animal housing and support areas. Each component is evaluated in the context of the Guide for the Care and Use of Laboratory Animals, the Animal Welfare Act, and the PHS Policy. A component judged compliant is marked in the "A" column. Those with minor deficiencies are marked in the "M" column. Those with significant deficiencies are marked in the "S" column. Minor and significant deficiencies must be detailed by component in the notes section.

Date of Evaluation				
Evaluators Printed Name Signat	ure			
	uno:			
Animal Housing and Support Areas (identity site)				
Criteria		A	Μ	S
1.0 Location		(· · · · · ·	
1.1 Animal areas separated from personnel areas		2		
1.2 Adequate separation of species		N I		
1.3 Separation by disease status		P		
2.0 Construction	$\overline{\langle}$	3		
2.1 Sealed walls, ceiling, doors of adequate size with floor sweeps		1		
2.2 Sealed corridor walls with bumper guards	<	1	:	
2.3 HVAC producing 10 air changes per hour in all animal rooms				
2.4 Adequate drainage		2		
2.5 Adequate power and lighting				
2.6 Noise attenuation of relevant species		1		
2.7 Appropriate temperature and humidity ranges for animal rooms		$\dot{\rightarrow}$		
3.0 Sanitation and waste disposal		$\overline{}$		
3.1 Adequate frequency of cage and rack changing				
3.2 Each room equipped with appropriate cleaning tools		2		
3.3 Timely removal of refuse from rooms and hallways.	$\neg \forall$	~		
3.4 Appropriate use of chemical disinfectants	$\neg \neg$	2		
3.5 Procedures for collection, storage and disposal of wastes		2		
3.6 Hazardous waste disposal program is in place		3		
3.7 Adequate procedures for disposal of carcasses	$\neg \neg \uparrow$,		
3.8 Adequate cleaning and sanitation of hallways and support areas	<u> </u>	;		
3.9 Appropriate monitoring of sanitation process	$\neg \neg$	5		



Animal Housing and Support Areas			127	of 241	·······	
Criteria		· ·				<u></u>
4.0 Animal housing, behavioral management, psychological well-being		A	<u>N</u>	1	S	
4.1 Animal caging is appropriate size according to USDA regs and Guide	-	$\overleftarrow{\mathcal{D}}$				
4.2 Bedding is appropriate to species and intended research purposes of animals		<u>p</u>	_		<u> </u>	
4.3 Functional and accessible water supply providing clean potable water	\geq	μ				
4.4 Adequate, clean, accessible food supply appropriate to the species	\geq	-μ				_
4.5 Psychological well-being program for primates in place with adequate records	>	₽—			- <u>-</u>	_
4.6 Pair housing of primates where possible and within experimental aims	5	Ð				_
4.7 Exercise and socialization program for dogs is in place with adequate records	<u>\</u>	З				_
4.8 Documented, IACUC-approved exceptions to normal SOP housing standards	\geq	μ_			·	_
4.9 Provision for undisturbed observation of animals	~	З				_
5.0 Food and bedding storage and use; water system	1-	ÞŹ –				4
5.1 Food and bedding stored on palates and removed from wall by 6 inches	-	\mathbb{H}^{-}	_		··	4
5.2 Food rotation system in place	\prec	<u>N_</u>				-
5.3 All primate and guinea pig food within 90 days of the milling date	-(9				_
5.4 All food other than primate or guinea pig food within 180 days of milling date		<u>P</u>		_ _		4
5.5 Perishable food is of adequate quality and appropriately stored		μ				-
5.6 Storage of food in sealed containers with labeled expiration dates	$-\frac{1}{2}$	<u> </u>				-
5.7 Appropriate feeding schedules	$\overline{}$	<u> </u>				-
5.8 Water supplied ad libitum unless restriction required by approved protocol	Y	J_				-
5.9 Water quality is adequate	J	$\underline{\mathcal{I}}$				-
6.0 Pest control program	\mathcal{A}	Ý_				-
6.1 Pest control program in operation	\mathcal{A}	<u> </u>				-
6.2 Mechanism for notifying investigators of chemical use that may impact research	\mathcal{H}	$\frac{1}{2}$			<u> </u>	-
6.3 Mechanism for restricting dispersion of chemicals and agents	+	<u> </u>				
7.0 Weekend, holiday and emergency care	\	<u>) </u>				
7.1 Schedule set for weekend and holiday care	₩	J			·	
7.2 On call list is accessible for emergency problems	\uparrow	<u>ر</u>	<u> </u>			ł
8.0 Animal identification and records	\uparrow	<u>J</u>				
8.1 Cage card program is in place and working	+	J	<u> </u>			
8.2 Individual medical records maintained for appropriate regulated species	\mathcal{H}	<u>]</u>	<u> </u>			
9.0 Genetics and nomenclature	╀	}				
9.1 Appropriate records maintained for genetically unique stocks	\mathbf{k}	J				
9.2 Appropriate nomenclature used in naming new genetic stocks	$\langle \psi$	L.,				
10.0 Personnel areas	┝	<u> </u>	l			
10.1 Locker rooms	≁	}				
10.2 Administration area	✦	;				
10.3 Breakrooms	A	1		- <u> </u>		
11.0 Specialized space considerations	13					
11.1 Receiving area	\mathcal{H}			<u> </u>		
11.2 Quarantine program	Ŗ)			-	
11.3 Isolation rooms	た					
11.4 Necropsy room	N 1.		·			
11.5 Radiology	μ	, 	·····			
	\mathbb{L}	'		[



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: Please indicate the item number and detail any minor or significant deficiencies noted.
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Coverniment Entern 2 2 2 7 Anno 2 7 Annual Review: Cagewash Facility

Revised 8/99

Instructions: This form is used in the semi-annual evaluation of the cagewash facility and procedures. Each component is evaluated in the context of the Guide for the Care and Use of Laboratory Animals, the Animal Welfare Act, and the PHS Policy. A component judged compliant is marked in the "A" column. Those with minor deficiencies are marked in the "M" column. Those with significant deficiencies are marked in the "S" column. Minor and significant deficiencies must be detailed by component in the notes section.

Date of Evaluation			
Evaluators Printed Name Signature	1911.19	. Ter Arr	<u>्र</u> स्थित्
Cagewash Facility (identify site >>>>>)	3		
Criteria	A	M	S
1.0 Construction			
1.1 Sealed walls and ceilings		1	
1.2 Adequate drainage			
1.3 Ease of access; doors sufficient size for equipment movement	5		
1.4 Sufficient space for workload			
1.5 Provision for safe bedding disposal and pre-wash activities			
1.6 Insulation of walls and ceilings or provision for sound attenuation			
1.7 Appropriate utilities (hot/cold water, steam, floor drains, electric power)		7	
1.8 Ventilation adequate for steam and fume dissipation			
1.9 Separation of clean and dirty side operations			
2.0 Operations			
2.1 Safety procedures and equipment (gloves, eye protection, rubber boots, scrubs,			
aprons)			
2.2 Warning signs adequate and appropriately posted			
2.3 Eyewash station in place			
2.4 Cagewash temperatures are monitored and recorded			
2.5 Autoclave function is monitored			
			4

NOTATION	S: Please indicate the item number and detail any minor or significant deficiencies noted.
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	eron from entering building stram
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All redactions on this page are pursuant to (b)(6) & (b)(7)(c).

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Annual Review: General Procedure Areas

Revised 8/99

Instructions: This form is used in the semi-annual evaluation of procedure rooms. Each component is evaluated in the context of the Guide for the Care and Use of Laboratory Animals, the Animal Welfare Act, and the PHS Policy. A component judged compliant is marked in the "A" column. Those with minor deficiencies are marked in the "M" column. Those with significant deficiencies are marked in the "S" column. Minor and significant deficiencies must be detailed by component in the notes section.

Date of Evaluation			- <u></u>	
Evaluators Printed Name	Sionafiira		e de la co	
Procedure Areas				
Location being evaluated:	<u></u>	<u> </u>	<u></u>	
		A	M	S
1.0 Drug Storage				
1.1 Drug are stored appropriately		1		
1.2 Drugs in use are in date	· · · · · · · · · · · · · · · · · · ·		13	
1.3 Adequate records for controlled substances		\Box		
2.0 Occupational health and safety	· · ·	3		
2.1 Gas cylinders immobilized	· .	}		<u> </u>
2.2 Sharps containers are regulation and appropriately used.		\sim		<u> </u>
2.3 Warning signs are posted as needed	/	5		
2.4 Chemical are stored appropriately				
2.5 Scavenging of anesthetic gasses, if required				
3.0 General sanitation		2		·
3.1 Carcass disposal adquate		÷		
3.2 Room is free of refuse or debris		$\hat{\gamma}$		
1.0 Equipment maintenance		2		
.1 Equipment in the room is operational and well-maintained		$\hat{\gamma}^{+}$		
.0 Room maintenance		<u> </u>		
.1 Room walls and ceilings are free of defects.		2		
.2 Lighting and ventilation are adequate.		<u>}</u>		
.0 Other Issues		<u> </u>		
.1		J		
.2				
eneral comments				
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All redactions on this page are pursuant to (b)(6) & (b)(7)(c).

Annual Review: Veterinary Medical Care

Revised 8/99

Instructions: This form is used in the semi-annual evaluation of veterinary medical care. Each component is evaluated in the context of the Guide for the Care and Use of Laboratory Animals, the Animal Welfare Act, and the PHS Policy. A component judged compliant is marked in the "A" column. Those with minor deficiencies are marked in the "M" column. Those with significant deficiencies are marked in the "S" column. Minor and significant deficiencies must be detailed by component in the notes section.

Date of Evaluation	
Evaluators	Printed Name Signature

Veterinary Care Program			
Criteria	A	M	S
1.0 Preventative medicine/procurement/transportation	<u> </u>		
1.1 Evaluation of animal vendors	Vi	····	
1.2 Procedures for lawful procurement of animals			
1.3 Lawful transportation of animals		+	
1.4 Procedures for entry clinical evaluation, quarantine, stabilization		+	
1.5 Separation of species; separation by health status; separation by source	$\overline{\langle}$		
1.6 Program for isolation of sick animals	$\overline{\mathbf{v}}$		
1.7 Program for surveillance, diagnosis, treatment and control of disease		-	
1.8 Availability of diagnostic resources for preventative health		·	
1.9 Provision for emergency, weekend and holiday veterinary care	1		
2.0 Surgery		_I	
2.1 Availability of appropriate training of personnel in anesthesia and surgery			
2.2 Presurgical plan includes space, supplies, pre- and post-op procedures	Χ.		
2.3 Procedures in place for monitoring anesthesia and analgesia			
2.4 Definitions distinguish major and minor procedures	V1		
2.5 Use of effective aseptic technique for survival surgeries			
2.6 Defined procedures for use of the surgical facility			
2.7 Procedures for using and scavenging volatile anesthetics			
2.8 Procedures for autoclaving surgical packs and monitoring expiration dates	, N		
2.9 Documentation of post-operative care		· /	
3.0 Pain, distress, analgesia, and anesthesia		1	
3.1 Guidelines for assessment and categorization of pain			
3.2 IACUC guidelines for avoiding unnecessary pain or distress	$-\psi$		
3.3 Appropriate anesthetics, analgesics, tranquilizers used for each species			
3.4 Paralytics not used without appropriate anesthetics to eliminate pain	- jų		
3.5Veterinary input on choice of drugs	$-\psi$		



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Criteria		
4.0 Euthanasia		
4.1 Use of the current guidelines of the AVMA Panel on Euthanasia		
4.2 Process of IACUC approval for alternative euthanasia methods	-	
4.3 Guidance provided on appropriate methods for each species		
4.4 Training in humane methods of euthanasia is available to personnel		
5.0 Drug storage and control		
5.1 Drugs stored in secure location, under appropriate conditions		<u> </u>
5.2 Records maintained according to regulations		————
5.3 Procedures for assurance that drugs are within expiration dates		

	Please indicate the item number and detail any minor or significant deficiencies note	<u>5a</u> .
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<u> -</u>		
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Annual Review: Aseptic Surgery

Revised 8/99

Instructions: This form is used in the semi-annual evaluation of the aseptic surgery program and facilities. Each component is evaluated in the context of the Guide for the Care and Use of Laboratory Animals, the Animal Welfare Act, and the PHS Policy. A component judged compliant is marked in the "A" column. Those with minor deficiencies are marked in the "M" column. Those with significant deficiencies are marked in the "S" column. Minor and significant deficiencies must be detailed by component in the notes section.

Evaluators Printed Name Signature				
		dianty say (si An	- Laterat in 190	
Aseptic Surgery Evaluation				
Criteria	6.1. 288 -	Α	M	S
1.0 General Considerations	<u></u>	1	<u></u>	P
1.1 Location minimizes traffic and contamination	$\overline{}$	5		1
1.2 Functional components such as surgical support, animal preparation, surgeon		<u> </u>	+	
scrub, operating room, and post-operative recovery are designed and separated from	n l			
one another, according to Guide recommendations.				
1.3 Appropriate drug storage, control, expiration data monitoring.			1	11
1.4 Safe sharps disposal		1		1
1.5 Adequate records of anesthesia and peri-operative care	$ \forall$	$\overline{)}$		
1.6 Aseptic procedures in use for all survival surgery	\checkmark	3		
1.7 All drugs in the facility are within the expiration dates			K1	
1.8 All suture materials and supplies are within the expiration dates		· · · · · · · · · · · · · · · · · · ·	1	
1.9 Component areas are clean, organized and stocked	$\overline{}$	1		
2.0 Operating Room	N	 ن		
2.1 Effective contamination control procedures	1	<u> </u>		
2.2 Effective cleaning procedures with dedicated tools		<u> </u>		
2.3 Interior surfaces smooth and impervious to moisture	1	<u>.</u>		
2.4 HVAC system meets Guide requirements (filtered air at positive pressure)	Ţ			
2.5 Lighting is safe and appropriate	7			
2.6 Outlets are safe and appropriate		$\overline{\mathbf{v}}$		
2.7 Gas anesthetic scavenging is in place	1	5		
2.8 Warning signs posted where needed	-/	5		
2.9 Fixed equipment is sanitizable	\mathbf{n}	1		
3.0 Surgical Support Areas	J	 ۱		
.1 Facility for washing, sterilizing, storing instruments and supplies	$\overline{)}$	J		
.2 Autoclave monitoring procedures are implemented	Y			
.3 Storage of autoclaved materials maintains sterility	1	J		
.4 Dating of autoclaved packs and supplies		1		
.5 Cold sterilization procedures are appropriate	\uparrow	5		



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Aseptic Surgery Evaluation	geotection et a	-134-of 241
Criteria		
4.0 Animal Preparation		MS
4.1 Contains sink and supplies to clean animal and operative site	- VK-	
4.2 Cabinets contain appropriate supplies and pre-anesthetic drugs	$-\gamma$	
5.0 Surgeon Scrub		
5.1 Located outside of the surgery room		
5.2 Foot or knee-operated sink	- <u> </u>	<u> </u>
6.0 Post-Operative Recovery	P	<u> </u>
6.1 Permits adequate observation of the animals	<u> </u>	
6.2 Area is easily cleaned	<u> </u>	
6.3 Area supports physiologic functions		
6.4 Area minimizes risk of injury during recovery	$-\underline{\mathcal{H}}$	
7.0 Dressing areas		
7.1 Dressing rooms available.	-	

NOTATIONS:	Please indicate the item number and detail any minor or significant deficiencies noted
	Please indicate the item number and detail any minor or significant deficiencies noted and of dall drug - supplies yound in procedure room
	in procedure room
· · · · · · · · · · · · · · · · · · ·	
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Semi-Annual Review: Investigator Laboratories

Revised 8/99

Instructions: This form is used in the semi-annual evaluation of investigator laboratories. Each component is evaluated in the context of the Guide for the Care and Use of Laboratory Animals, the Animal Welfare Act, and the PHS Policy. A component judged compliant is marked in the "A" column. Those with minor deficiencies are marked in the "M" column. Those with significant deficiencies are marked in the "S" column. Minor and significant deficiencies must be detailed by component in the notes section.

Date of Evaluation			. <u> </u>
Evaluators	Printed Name Signature		
			-
PI Last Name	· · · · · · · · · · · · · · · · · · ·		
Protocol Number			
Protocol Title			
Building and Room			ù
Phone Number			
Acknowledged by:		<u> </u>	
1.0 Use of animals in the laborato		Yes	No
Are animals used or held in the labo			
Are animals held in the laboratory g	reater than 12 hours?		<u> </u>
Are surgical procedures done in the	laboratory? If yes, please note what procedures below	w	<u></u>
Are animals euthanized in the labora	atory?		<u> </u>
What species are used in this laborat	ory?	<u></u>	<u> </u>
Criteria		A M	S
2.0 Methods of euthanasia		· · ·	
2.1 Indicate the method of euthanasi	a being used		
2.2 Method of euthanasia with AVM	IA Panel Guidelines		
2.3 Personnel trained in the euthanas	ia method		- <u></u>
3.0 Anesthesia and surgery		l,	L
3.1 Sterile instruments available			· · ·

3.2 Method of sterilization is adequate to kill organisms3.3 Sterile gloves available for surgical procedures

3.4 Surgical scrubs and materials available for site preparation

3.5 All drugs, sutures, supplies and materials are in date (USDA Policy #3)3.6 All scheduled drugs are maintained under lock-down with appropriate logs

 3.7 Anesthetics currently in use
 Yes
 No

 3.7.1 Injectable anesthetics
 3.7.2 CO₂/O₂ anesthesia
 9

 3.7.3 Ether anesthesia
 9
 9

 3.7.4 Halothane/metofane/aerraine anesthesia
 9
 9

3.7.5 Gas anesthetic scavenging is adequate



3.7.6 Adaquate post surgical records are extant (SOP PROG 13, SOP VET	Γ4)	36 of 241	[
4.0 Holding of laboratory animals >12 hours		M	S
4.1 Adequate caging is available		141	
4.2 Temperature range is acceptable (68-78° F)			
4.3 Food, water, and bedding are acceptable			
4.5 Light dark cycling is in place			

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NOTATIONS:	Please indicate the item number and	detail any minor or significant deficiencies noted.
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<u> </u>		

PLEASE NOTE WHAT SURGICAL PROCEDURES ARE BEING DONE IN THIS LABORATORY.



University of Kansas Medical Center Institutional Animal Care and Use Committee Investigator Laboratory

Principal Investigator			stitutional Animal Care an	out of the second section of the second section of the second second second the second section section second section second second section second section second section second section second section s	tion Report		
		Use of Animals in Lab	Euthanasia Methods	Anesthesia and Surgery			
First Name Last Name	Buliding Room	4			10	Separating	
(b	-	"1 "1 "1	Euthanasia N N	-	Held In Lab	b Space	F¢
)(6)(2	2005-1511 Y N Y Y Frogs	A A	2°E 2°E 2°E	ъ ъ ъ т	to to broceduroo	H ^{rotes}
), ()Hi	Mice				A A A VILLE	16
b)(gh	Eggs					-54
7)(&	2004-1472 Y N N V Mice					9
C)	(b)(Isoliourare A A	A A N N N Y Y		-	
	(7)(V V	
	F)	ZUUG-1548 Y N N Y Rats	Isoflourance A A	_;			
	1	Mice		2	A A	AA	
		2007-1632 Y N N Y Mice					
	<u> </u>			A A N N N N N		-	
			rencoarbital			AA	
		2007-1631 Y N N Y Mice					
	1		Pentobarbital	A A N N N N N		A A	
						:	
		2005-1522 Y N N Y Mice	Mice cocktail A A	:			
					A	AA	loos ar
							but person
	1						absent & car
		Rats	Pentobarbital				locked
							Kevs are ken
		-					but person
	1		•				absent & can
	ł						access - is
		2007-1630 Y N N Y Mice	Mouse cocktail or A A				locked
	1				A	AA	
	1						
		AUGULIDID I N N Y MICE	Mouse cocktail or A A	N N N N			
			pentobarbital	2	4	AA	logs are kept,
		· ·					but person
							absent & can
							access - is locked
							Kevs are kent
							but person
	1		-				absent & can'
							access - is
		2005-1485 Mice	Halothene/cervica				locked
	1		l disloc				
		· .					
		T N Y Mice	Halothene/cervica A A A	A A A A Y N N Y N			
			I disloc		× 	A A	Recover-ant.
			-				Eye chamber
							graft, renal
							isuocapsular Oraft//Nonrecor
-							ery-embryo
							collection,
							nephrectomy
		2006-1561 Y Y N Y rats	Isoffurane. A A				f 2:
			nation		AAAA	AA	41
	1						

2/5/2008 Investigator Lab Inspection Spreadsheet -blank.xls

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Ś University of Kansas Medical Center Institutional Animal Care and Use

Principal Investigator			valisas Medical Center In	or valisas medical Center Institutional Animal Care and Use Committee Investigator Laboratory Inspection Report	
			Use of Animals in Lab		
First Name Last Name	Building Room	Protocol #	1 2 3		
(t			" " 	Eutranasia 2 2 2 3 3 4 5 5 7 7 7 7 6 6 7 7 9 2 9 2 6 7 7 7 7 6 6 7 7 9 2 7 7 7 7 7 6 6 7 7 9 2 7 7 7 7 9 1 7 9 1 7 9 1 7	
)(6)(2)	>	2 3 5 7 7 7 7 7 7 7 7 7 7 7 7 7	seiotes
), (t			2		
))(7		5005 IE40	> 		540
)(C)				cervical A A A A A A A Y N N N A A A A A A Y N N N A A A A	
		7)(F			
·		2004-1468	Y N Y Y rats		
				anguishation	
		2004-1470	Y Y Y Primates	pentobarbitaliexs A A A A A A A A A A A V N N V V V	
				anguishation	
		2004-1477	Y Y Y Primates	pentobarbital/exs A A A A A A A A V N V V V	
		2007-1658	Y Y Y Y primates	pentobarbital/exs A A A A A A A Y N N V V V V	
		2007-1621	Y N Y Y rats		
		2006-1568	Y Y N Y rats	AvertityExsanctive	
		2005-1503	N N N Rats	A A A A A A A A A X N N N N A A A A A A	
		2006-1569	Y Y N Y mice	lefthoraix A A	
		_	-		
		2006-1536	Y N Y Y rats	uthanasia/deca A A A A A A A Y N N N N N	
		2005-1527	Y N Y Mice	A A A A A A A N N N N N N N N N N N N N	
		2005-1497	Y N Y Y froas		
			5	anesthesia	
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2/5/2008 Investigator Lab Inspection Spreadsheet -blank.xls



Il redactions on this page are pursuant to (b)(6) & (b)(7)(c).

The University of Kansas Medical Center



Institutional Animal Care and Use Committee , PhD, Chair

MEMORANDUM

То:	JD, MPH Associate Vice Chancellor for Compliance
From:	Ph.D. Chair, Institutional Animal Care and Use Committee
Subject:	Semi-Annual Evaluation of Program and Facilities Report to the Institutional Official
Date:	June 17, 2008

This memorandum represents the semiannual report of the Institutional Animal Care and Use Committee (IACUC) as required by the PHS Policy on Humane Care and Use of Laboratory Animals and as a condition of this institution's Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW) and USDA Animal Welfare Regulations. These regulations require that the IACUC review the University's animal care and use program and facilities every 6 months and provide a summary of this review to the University's Institutional Official. The IACUC conducted its semiannual evaluation of the institution's animal care and use program during the months of May and June. This review included visits of individual investigator laboratories and assessment of the animal facilities and programs.

Evaluation of Individual Investigator Laboratories

Committee members visited individual laboratories in the months of May and June to inspect their facilities, discuss animal care, adherence to protocols, and educate investigators and staff on compliance issues. Particular emphasis was placed on training; knowledge of the protocol, including review of approved procedures; changes requiring addenda; AVMA approved methods of euthanasia and proper management of scheduled drugs. No serious deficiencies or issues of noncompliance were identified. Some minor deficiencies were noted including expired drug found in four labs, out of date surgical supplies found in one lab, and sterile gloves were not available for survival surgical procedures in two labs. These issues were resolved the day of or shortly after the day of inspection or are in the process of being corrected. All corrections should be completed by the July IACUC meeting.

Evaluation of the Animal Care and Use Program

A four-member subcommittee reviewed the animal facilities and programs on May 15, 2008, and concluded the overall organization of the program to be in compliance with all federal requirements. The committee inspected all animal facilities in the Building 30, Kansas Life



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Sciences Innovation Center (KLSIC), and Smith, as well as satellite facilities in the Hoglund Brain Imaging Center and Wahl Hall East.

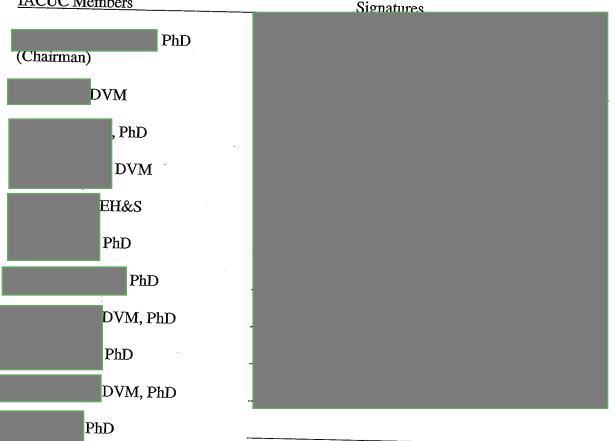
The committee found the general condition of all facilities satisfactory and was impressed with the overall appearance and cleanliness of all three buildings. No significant deficiencies were identified during the review. The following minor deficiencies were noted. Feed was stored less than six inches from the wall in Building 30, KLSIC and Smith, Biohazard sheets in two animal housing rooms needed updated emergency contact information, chipped paint was found in rat housing room in the LAR, and expired sodium chloride was found in a procedure room. The minor issues listed above have all been corrected with the exception of the chipped paint. Due to space restrictions, increased rodent populations, and construction there is no room to rotate animals to another room until the painting is complete. This room will be repainted once the construction of the new cagewash is complete this fall.

Repairs and renovations of the cagewash will be done in conjunction with federally funded replacement of the cagewash equipment this fall and there are animal housing areas with no provision for undisturbed observation of animals because a few rooms do not have windows in them.

Minority Views

There were no minority views from the IACUC committee regarding the semiannual review or report.

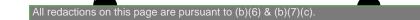












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Annual Review: Animal Housing and Support Areas

Revised 8/99

Instructions: This form is used in the semi-annual evaluation of animal housing and support areas. Each component is evaluated in the context of the Guide for the Care and Use of Laboratory Animals, the Animal Welfare Act, and the PHS Policy. A component judged compliant is marked in the "A" column. Those with minor deficiencies are marked in the "M" column. Those with significant deficiencies are marked in the "S" column. Minor and significant deficiencies must be detailed by component in the notes section.

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Animal Housing and Support Areas (identify site)		·······		
Criteria		A	M	\ S
1.0 Location			1	
1.1 Animal areas separated from personnel areas	~			<u> </u>
1.2 Adequate separation of species		} ⊃		
1.3 Separation by disease status		<u> </u>		
2.0 Construction		<u></u>	<u> </u>	
2.1 Sealed walls, ceiling, doors of adequate size with floor sweeps	<u></u>			
2.2 Sealed corridor walls with bumper guards		L	<u> </u>	
2.3 HVAC producing 10 air changes per hour in all animal rooms	~	V		
2.4 Adequate drainage				
2.5 Adequate power and lighting				
2.6 Noise attenuation of relevant species	~	<u> </u>		
2.7 Appropriate temperature and humidity ranges for animal rooms		<u>ل</u>		
3.0 Sanitation and waste disposal	· · · · · · · · · · · · · · · · · · ·	-		······
3.1 Adequate frequency of cage and rack changing	~	-		
3.2 Each room equipped with appropriate cleaning tools	~	ر		
3.3 Timely removal of refuse from rooms and hallways.)		
3.4 Appropriate use of chemical disinfectants	/	<u>،</u>		
3.5 Procedures for collection, storage and disposal of wastes	/	1		
3.6 Hazardous waste disposal program is in place	$\neg \neg$	Ĭ		
3.7 Adequate procedures for disposal of carcasses		5	·	
3.8 Adequate cleaning and sanitation of hallways and support areas	$\neg \neg$	ī		
3.9 Appropriate monitoring of sanitation process	$\neg \neg$	J		
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0.5.3 Mitchanism for restricting dispersion of chemicals and agents	6.2 Mechanism for notifying investigators of chemical use that may impact research	Ŧ					-
7.0 Weekend, holiday and emergency care	0.5 Mechanism for restricting dispersion of chemicals and agents	7	<u>ر</u> ،			<u> </u>	\dashv
7.1 Schedule set for weekend and holiday care 7.2 On call list is accessible for emergency problems 8.0 Animal identification and records 8.1 Cage card program is in place and working 8.2 Individual medical records maintained for appropriate regulated species 9.0 Genetics and nomenclature 9.1 Appropriate records maintained for genetically unique stocks 9.2 Appropriate nomenclature used in naming new genetic stocks 10.1 Locker rooms 10.2 Administration area 10.3 Breakrooms 11.1 Receiving area 11.2 Quarantine program 11.3 Isolation rooms	7.0 Weekend, holiday and emergency care	F	J				-
7.2 On call list is accessible for emergency problems	7.1 Schedule set for weekend and holiday care	+		-			-
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10.3 Breakrooms J 11.0 Specialized space considerations J 11.1 Receiving area J 11.2 Quarantine program J 11.3 Isolation rooms J 11.4 Necropsy room J	10.1 Locker rooms	+					4
10.3 Breakrooms J 11.0 Specialized space considerations J 11.1 Receiving area J 11.2 Quarantine program J 11.3 Isolation rooms J 11.4 Necropsy room J	10.2 Administration area	\geq	3		_+-		-
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1.3 Isolation rooms 1.4 Necropsy room	11.2 Quarantine program	4					4
	11.3 Isolation rooms	\downarrow					-
	11.4 Necropsy room	Ą	└──┼				-
	11.5 Radiology	¥					-

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N/591/2 1915	152 of 241
HOIAI	52 of 241 5NS: Please indicate the item number and detail any minor or significant deficiencies noted
	Mupped paint 106/ LAR
······································	c) road needs to be moved away from weel
	Dehipped paint 1010/ LAR 2) Food needs to be moved away from wall in KLSIC, LAR - MARC
	3) Buchazzard sheets in 3027+3028 in the LAR nuds to be updated with current Contact into for PI.
	142 rads to be updated with formand
	Contact into for Pl.
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Page 6 of 37	7 .
Page 6 of 37	
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FOIA 10-549

Annual Review: Veterinary Medical Care

Revised 8/99

Instructions: This form is used in the semi-annual evaluation of veterinary medical care. Each component is evaluated in the context of the Guide for the Care and Use of Laboratory Animals, the Animal Welfare Act, and the PHS Policy. A component judged compliant is marked in the "A" column. Those with minor deficiencies are marked in the "M" column. Those with significant deficiencies are marked in the "S" column. Minor and significant deficiencies must be detailed by component in the notes section.

Date of Evaluation	5115708
Evaluators	Printed Name Sionature

Veterinary Care Program				
		A	M	S
1.0 Preventative medicine/procurement/transportation		<u>] 1</u>	141	<u> </u>
1.1 Evaluation of animal vendors		Τ	7	
1.2 Procedures for lawful procurement of animals		+	+	·
1.3 Lawful transportation of animals	— <u>``</u>	<u>}_</u>	++	
1.4 Procedures for entry clinical evaluation, quarantine, stabilization		5		·
1.5 Separation of species; separation by health status; separation by source		$\overline{\Sigma}$	╄───┼	
1.6 Program for isolation of sick animals		5	╉────╁	
1.7 Program for surveillance, diagnosis, treatment and control of disease		5	╞───┼	
1.8 Availability of diagnostic resources for preventative health		<u>t</u>	┼───┼	
1.9 Provision for emergency, weekend and holiday veterinary care		Č—	 	
2.0 Surgery	~ <u> </u>	<u> </u>	L	
2.1 Availability of appropriate training of personnel in anesthesia and surgery				
2.2 Presurgical plan includes space, supplies, pre- and post-on procedures	~	J	<u>├───</u> ├	
2.3 Procedures in place for monitoring anesthesia and analgesia				
2.4 Definitions distinguish major and minor procedures				
2.5 Use of effective aseptic technique for survival surgeries		3	 	
2.6 Defined procedures for use of the surgical facility	\neg	J		
2.7 Procedures for using and scavenging volatile anesthetics		.		
2.8 Procedures for autoclaving surgical packs and monitoring expiration dates		J	—— <u> </u> -	
2.9 Documentation of post-operative care	$\neg \uparrow$			
3.0 Pain, distress, analgesia, and anesthesia		4 L	<u> </u>	
3.1 Guidelines for assessment and categorization of pain				
3.2 IACUC guidelines for avoiding unnecessary pain or distress	\rightarrow			
3.3 Appropriate anesthetics, analgesics, tranquilizers used for each species	$\neg \forall$	<u>,</u>		
3.4 Paralytics not used without appropriate anesthetics to eliminate pain				
3.5Veterinary input on choice of drugs	\rightarrow			



FOIA 10-549	154 of 241
Criteria	A M S
4.0 Euthanasia	
4.1 Use of the current guidelines of the AVMA Panel on Euthanasia	
4.2 Process of IACUC approval for alternative euthanasia methods	
4.3 Guidance provided on appropriate methods for each species	
4.4 Training in humane methods of euthanasia is available to personnel	
5.0 Drug storage and control	
5.1 Drugs stored in secure location, under appropriate conditions	
5.2 Records maintained according to regulations	
5.3 Procedures for assurance that drugs are within expiration dates	

NOTATION	IS: Please indicate the item number and detail any minor or significant deficiencies noted.



All redactions on this page are pursuant to (b)(6) & (b)(7)(c).

FOIA 10-549

Annual Review: Aseptic Surgery

Revised 8/99

Instructions: This form is used in the semi-annual evaluation of the aseptic surgery program and facilities. Each component is evaluated in the context of the Guide for the Care and Use of Laboratory Animals, the Animal Welfare Act, and the PHS Policy. A component judged compliant is marked in the "A" column. Those with minor deficiencies are marked in the "M" column. Those with significant deficiencies are marked in the "S" column. Minor and significant deficiencies must be detailed by component in the notes section.

Date of Evaluation SINTO8
Evaluators Printed Name Signature

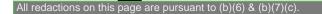
Aseptie Surgery Evaluation Criteria 1.0 General Considerations 1.1 Location minimizes traffic and contamination 1.2 Functional components such as surgical support, animal preparation, surgeon scrub, operating room, and post-operative recovery are designed and separated from one another, according to Guide recommendations. 1.3 Appropriate drug storage, control, expiration data monitoring. 1.4 Safe sharps disposal 1.5 Adequate records of anesthesia and peri-operative care 1.6 Aseptic procedures in use for all survival surgery 1.7 All drugs in the facility are within the expiration dates 1.8 All suture materials and supplies are within the expiration dates 1.9 Component areas are clean, organized and stocked 2.0 Operating Room 2.1 Effective cleaning procedures with dedicated tools 2.3 Interior surfaces smooth and impervious to moisture 2.4 HVAC system meets Guide requirements (filtered air at positive pressure) 2.5 Lighting is safe and appropriate 2.6 Outlets are safe and appropriate 2.7 Gas anesthetic scavenging is in place 2.8 Warning signs posted where needed 2.9 Fixed equipment is sanitizable 3.0 Fixed equipment is sanitizable 3.1 Facility for washing, sterilizing, storing instruments and supplies	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
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3.1 Facility for washing, sterilizing, storing instruments and sumplies		
3.1 Facility for washing, sterilizing, storing instruments and guanties		
a a har supplies		
5.2 Autoclave monitoring procedures are implemented		
3.3 Storage of autoclaved materials maintains sterility		
3.4 Dating of autoclaved packs and supplies		
3.5 Cold sterilization procedures are appropriate		



Aseptic'stilgery Evaluation	1	56 of 241	l
Criteria			
4.0 Animal Preparation	A	M	S
4.1 Contains sink and supplies to clean animal and an anti-			
4.2 Cabinets contain appropriate supplies and pre-anesthetic drugs			
Sto Surgeon Scrub			
5.1 Located outside of the surgery room			
5.2 Foot or knee-operated sink			
6.0 Post-Operative Recovery			
6.1 Permits adequate observation of the animals			
0.2 Area is easily cleaned			
6.3 Area supports physiologic functions			
6.4 Area minimizes risk of injury during recovery			
7.0 Dressing areas			
7.1 Dressing rooms available.			

NOTATIO	NS: Please indicate the item number and detail any minor or significant deficiencies noted
	i) Out of date heparin in Hogwood 2) Out of date sodium chloride in procedere roome (3020) in LAR





FOIA 10-549

Annual Review: General Procedure Areas

Revised 8/99

Instructions: This form is used in the semi-annual evaluation of procedure rooms. Each component is evaluated in the context of the Guide for the Care and Use of Laboratory Animals, the Animal Welfare Act, and the PHS Policy. A component judged compliant is marked in the "A" column. Those with minor deficiencies are marked in the "M" column. Those with significant deficiencies are marked in the "S" column. Minor and significant deficiencies must be detailed by component in the notes section.

Date of Evaluation 5718108 Evaluators Printed Name Signat			
Evaluators Printed Name Signat	ure		
	<u></u>		2508,00
		<u></u>	
Procedure Areas	ويعمر فكعرب الكرور والترا		
Procedure Areas Location being evaluated:			
			1
Criteria 1.0 Drug Storage	A.	M	S
1.1 Drug are stored appropriately		┿──┤	<u> </u>
1.2 Drugs in use are in date	<u>></u>		
1.3 Adequate records for controlled substances	`	<u>↓</u>	·····
2.0 Occupational health and safety	<u> </u>	₋	
2.1 Gas cylinders immobilized			<u>.</u>
2.2 Sharps containers are regulation and appropriately used.	<u> </u>	╪╼═╍┼	<u> </u>
2.3 Warning signs are posted as needed.	<u> </u>	╉───┤	······
2.4 Chemical are stored appropriately	<u> </u>	++	
2.5 Scavenging of anesthetic gasses, if required	<u> </u>	┢───┤	
3.0 General sanitation	_	++	,,,
3.1 Carcass disposal adquate		┼──┼	
3.2 Room is free of refuse or debris		┼───┼	
4.0 Equipment maintenance	<u>P</u>	┼	
4.1 Equipment in the room is operational and well-maintained		┼──┝	
5.0 Room maintenance	<u> </u>	+	
5.1 Room walls and ceilings are free of defects.		┼┼	
5.2 Lighting and ventilation are adequate.	$-\overline{\downarrow}$	┟───┼	
6.0 Other Issues			
6.1		<u>├</u>	
5.2		LL	
General comments			
Hout of date soder chloride in 3000 LAR + OUT of a	late has	201 (1 ~	
is Abstund.	- ep	mil)	<u> </u>



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FOIA 10-549Annual Review: Institutional Polices and Responsibilities

Revised 8/99

Instructions: This form is used in the semi-annual evaluation of institutional polices and responsibilities. Each component is evaluated in the context of the Guide for the Care and Use of Laboratory Animals, the Animal Welfare Act, and the PHS Policy. A component judged compliant is marked in the "A" column. Those with minor deficiencies are marked in the "M" column. Those with significant deficiencies are marked in the "S" column. Minor and significant deficiencies must be detailed by component in the notes section.

Date of Evaluation				
Date of Evaluation Evaluators				····· _··· _·· _·· _·
Evaluators Printed Name O Signature.	1. ¹ .	_		
			<u> </u>	- <u></u>
			<u> </u>	
		<u> </u>		
1.0 IACUC membership and functions		A	M	S
1.1 Minimum of 5 members, appointed by the institution 1 of the		<u> </u>	<u> </u>	
and strontoold monitor verennarian dotontiat		2		
	\geq	5		
	_	4		
1.5 Conducts semi-annual evaluations of animal care and use program	<u> </u>	N		
1.6 Conducts semi-annual evaluations of animal facilities		\mathbf{V}		
1.7 Reviews and investigates concerns of animal facilities		5		
1.7 Reviews and investigates concerns about animal care and use at the institution	Y	J		
	Z	1		
1.9 Procedures for review and approval and suspension of animal activities 1.10 Policies for special procedures (regraining and the second sec	1	/		
	ム			
	-+			
2.1Reports to the institutional official (IO)	-			
2.1.1 Reports of semi-annual reviews and facilities inspections to IO	4	, ,		
and mondors minority views of IAC IC mombane	Ł			
2.1.3 Describes departures from Guide or PHS Policy and reasons for departure	Ł			
	Ϋ́			
2.1.3 include a plan and schedule for correction of each 1 C	1			
and Reports to Office for Profection from Descendent 1 (OPP-	Ψ			
Think in the second sec	\perp			
2.2.2.1 milluar report documents changes: giving data	Ψ			
	4			
2.2.4 Promptly adivses OPRR of any suspension of activity by the IACUC	4			
of first of any suspension of activity by the IACUC	15			



Criterfa ¹⁰⁻⁵⁴⁹		159 of 24	1
2.3 Reports to the United States Department of Agriculture	A	Μ	, L
2.3.1 Aunual 10001 containing required informat			
2.5.2 Reporting mechanism in place for IA CUIC and the second sec	<u>\</u>		
	$\psi_{}$		
2.3.4 Reports IACUC-mandated suspension of activity to USDA and any federal funding agency	4		
2.3.5 Minutes of IACUC meetings and some area 1	2		
	2		
2.3.7 IACUC review of activities involving animals includes all required	u I		
information			
3.0 Veterinary Care	\sim		
3.1 Veterinarians with training on annuit in the			
3.1 Veterinarians with training or experience in lab animal medicine available 3.2 Veterinarians have access to all animals	4		_
3.3 Provision for back-up veterinary care	L		
3 4 Availability of midance in 1	<u> </u>		
3.4 Availability of guidance in handling, immobilization, sedation, anesthesia, analgesia			
	J L		
3.5 Guidance and oversight of surgery programs and post-surgical care			
and interventional of animal and and and and	1		
4.0 rersonner Qualifications and Training			·
4.1 Institution has established and implemented an effective training program			
and the second sec			
4.4 Training includes research investigators, instructors, technicians, trainees,			<u>-</u>
4.J Training Program Content			
4.5.1 Humane practices of animal care (housing, husbandry, handling)			
Truthano practices of animal nee (gurgowy on sult)	<u> </u>		
the saturation of animal state in the second s			
t.J.4 Research/testing methods that minimize pain or distance			
r.s.s Hazaru communication program			
5.0 Occupational Health and Safety of Borrows L			··
1 Institutional Program for a Safe and Healthry Weyl 1			
.1.1 I logialli is established and implemented			
.1.2 Covers all personnel who work in laboratory animal for itig			
.1.5 I logialli is based on hazard identification and rist			
.1.4 Training in specific hazards (zoonoses, pregnancy, un-defined illnesses, etc.)			
1.5 Personal hygiene procedures and equipment			
1.6 Procedures for storage, use and disposal of hazardous agents			
1.7 Specific Procedures for personnal protocities (1)			
1.7 Specific Procedures for personnel protection (shower, change facilities, injury revention)			
1.8 MSDS available through the institution			
The HADD'S available through the institution			-



Criteria 10-549			160 of 24	1
		A	M	S
5.2 Program for medical evaluation and Preventative Medicine for Personne	1			
5.2.1 Elliployment evaluation including health history		†	<u> </u>	
5.2.2 Immunizations as appropriate (rabies, tetnus) plus any tests needed		2 ——		
5.2.3 Zoonosis surveillance as needed	\geq	μ		
5.2.4 Procedures for remarking 1/	~	L)		
5.2.4 Procedures for reporting and treating injuries (exposure control)		٦		
5.3 Special Precautions for Personnel Working With Primates				
5.3.1 Tuberculosis screening		、		
5.3.2 Exposure control program for bites, scratches, needle sticks, etc.	\rightarrow		· .	
5.3.3 Education regarding Cercopithecine herpesvirus 1 (Herpes B)	$ \ge$	3		
Herpes B)	\neg	5		

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· ·	NS: Please indicate the item number and detail any minor or significant deficiencies note
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FOIA 10-549



Annual Review: Investigator Laboratories

Revised 8/99

Instructions: This form is used in the semi-annual evaluation of investigator laboratories. Each component is evaluated in the context of the Guide for the Care and Use of Laboratory Animals, the Animal Welfare Act, and the PHS Policy. A component judged compliant is marked in the "A" column. Those with minor deficiencies are marked in the "M" column. Those with significant deficiencies are marked in the "S" column. Minor and significant deficiencies must be detailed by component in the notes section.

Date of Evaluation			
Evaluators	Printed Name	Signature	

PI Last Name	
Protocol Number	· · · · · · · · · · · · · · · · · · ·
Building and Room	· · · · · · · · · · · · · · · · · · ·
Phone Number	
Acknowledged by:	

1.0 Use of animals in the laboratory	Yes	No
Are animals used or held in the laboratory?		
Are animals held in the laboratory greater than 12 hours?		
Are surgical procedures done in the laboratory? If yes, please note what procedures below		
Are animals euthanized in the laboratory?		
What species are used in this laboratory?		
Criteria A	M	S
2.0 Methods of euthanasia		
2.1 Indicate the method of euthanasia being used		
2.2 Method of euthanasia with AVMA Panel Guidelines		
2.3 Personnel trained in the euthanasia method	<u> </u>	
3.0 Anesthesia and surgery		·
3.1 Sterile instruments available	_	
3.2 Method of sterilization is adequate to kill organisms		L
3.3 Sterile gloves available for surgical procedurdes		
3.4 Surgical scrubs and materials available for site preparation		
3.5 All drugs, sutures, supplies and materials are in date (USDA Policy #3)		
3.6 All scheduled drugs are maintained under lock-down with appropriate logs		
3.7 Anesthetics currently in use	Yes	No
3.7.1 Injectable anesthetics		
$3.7.2 \text{ CO}_2/\text{O}_2$ anesthesia		
3.7.3 Ether anesthesia		
3.7.4 Halothane/metofane/aerraine anesthesia		
3.7.5 Gas anesthetic scavenging is adequate		
3.7.6 Adequate post surgical records are extant (SOP PROG 13, SOP VET 4)		



4.0 Holding of laboratory animals >12 hours	A	16 p/p f2	41 S
4.1 Adequate caging is available			
4.2 Temperature range is acceptable (68-78° F)			
4.3 Food, water, and bedding are acceptable			
4.5 Light dark cycling is in place			

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5.0 Separation of animal use areas from other activities	A	M	S
5.1 Animal use areas are separated from other lab functions and office space			
5.2 Sanitation of animal use areas is adequate			
5.3 Disinfectants and cleaning agents are present in the laboratory			

NOTATIONS	: Please indicate the item number and detail any minor or significant deficiencies noted.

PLEASE NOTE WHAT SURGICAL PROCEDURES ARE BEING DONE IN THIS LABORATORY.



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Investigator Lab Inspection Spreadsheet- spring 2008.xls

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University of Kansas Medical Center Institutional Animal Care and Use Committee Investigator Laboratory Inspection Report

Investigator Lab Inspection Spreadsheet- spring 2008.xts

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2)		b)(7)(F)	2007-1657	۲ ۲	z		sters	CO2/decapitation A										<u>≻</u>								
				z ≻	z	Mice		CO2/decapitation A	4	·			۷	×	z	z		<u>}</u>			-	<pre></pre>	<u>ح</u>			Pentabarb out of date, but used only for euthanasiz. Procedure not in use-w drug if procedure resumes
			2005-1517	z ≻	z	Y Mice		CO2/cardiac	A			A	A	7	z	z	z	≻	· 			4	A A	Suhmandibalor II blood collection, p tail vien bleed	alor IAC tion, plex d anir	IACUC staff please verify animal users
		T																-					\vdash			
·					z	≺ Mice		CO2/Cervical disclosure/exsang uination/pentpbar bital	۲ ۲				۲	≻ V	z	z	z z	~				A A	۲ ۲			
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					z			Co2/pneumothora A x/pentabarbital	₹			Α	A	<u>ک</u>	z	z	z z	>				4	۲ ۲	Blood collection:mandi bular bleed, retro-orbital puncture	andi	
			2006-1595	<u>z</u> ≻	z	Y Mice			۲ ۲			A	A	≻	z	z	z z	7			_	A	A A	None-this	Ket	tAce /
					······································		<u><u><u></u></u></u>	dislocation/penta barbital	·····			<u> </u>					······································		······································					protocol has not appropria yet begun to be a method of euthanasia, even with a 2 degree metho irene says use as preliminary step to blood , followed by collowed by dispertion	degeeeert degeeeert degeeeert degeeeert degeeeert	appropria a method of evuthanasia, evuthanasia, evuthanasia, degree metho degree metho degree metho lirene says us as preliminary us tep to blood y followed by followed by
			2006-1576	z ≻	>	Y Rats		Decap or A CO2/cerv. Dislocation	A A	۲ ۲	A	A	A	<u></u>	z	z	z z	۲				A A	۲ ۲	Ovariectomy- done in Lied (not RSF)		Done in room 3046 (not 307

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Investigator Lab inspection Spreadsheet- spring 2008.xls 6

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	Principal Investigator	stigator				–	lse of ,	Anima	Use of Animals in Lab	Euthanasia Methods	Aethod	ş			Ăn	Anesthesia and Surgery	ia anc	1 Surg	ery				Time Animals	imals	-	Separating	Бu		
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Principal	Principal Investigator					Use	of A	nimal	Use of Animals in Lab	Euthanasia Methods	spor				Anesthesia and Surgery	Anesthesia and Surgery	ia an	d Sur	gerv			F	j i	e An	Time Animals		Senarating	tina		-	
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	7)(c)		& (b)(7)	2007-1688		≻ ≻	≻	≻		Pentabarb/perfusi A on/or decapitate	۲ ۲	۲	۲ ۲	۲ ۲	₹	<		<u>ک</u>	z z	≻ _	Y		A A	<u>م</u>	A	4	A	4	Craniotomy/infa rct induction	ta I	
			(F)	_	-				Rats						-			+		+	_		+		╞	+		\bot		-	
				2007-1658						Pentabarb/exs/pe A rfusion		۲	4	A A	A I	٩		<u>ح</u> ۲	z z	×	7	~	۲ ۲	4	4	4	4	Z 0 0	Craniotomy/chr onic electrode implants	2	
				1-cnnz				×		Halothane to A open chest cavity	<							z	z z	≻	≻					۲	4	A A	Tissue collection only		
				2005-1527						CO2/decapitation/ A Avertin/Intracardi ac perfusion	V V	4	4	< <	A I	٢		~	z	z ·		>				4	۲	A T	Introacochlear		
				2005-1506	206 ≺	z	z	z	Primates		۲															∢	A	A A	this protocol is currently not in		
														·				·				· · · · · ·				·		<u> </u>	use; experiments ended 4		
						┽┥	+									_								+	_			<u> </u>	months ago		
				2005-1507	507 Y	2	z	z	Drimatoe	Euthonocio						-	Ľ				\square		\uparrow	┢╌╽	┼┦						
											₹	٢	<	<	<	· · · · · · · · · · · · · · · · · · ·		z	z	z		≻				۹	٢	▲	Electrode implant, head restraint implant, recording chamber implant	Euthania Euthania Performen Perinson were uns were uns method in traint the method. LAR Van Acki van Acki needs to added to	Euthanasia-on this protocol is performed by I performed by I personnel in It were unsure of method and d inot performat in performat in performat in performat in performat in the method and d in the LARSuta gical reconcluta gical reconcluta van Acker needs to be added to user
				2006-1568	568 Y	<u>></u>	<u>></u>	>		Avertin A			▼		-	<	Í		-			>			_	-				_	
							·			overdose/perfusio n						<u>د</u>		-	2 -	z		F				۲.	<	⊐ a E ≺	ERG- electroretinogra m	170 	
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University of Kansas Medical Center Institutional Animal Care and Use Committee Investigator Laboratory Inspection Report

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Flist Name Last Name	Building	(p)	Room Protocol #	1.1 3		1.1	ies	Euthanasia Method			1.E 2.E			8.C 9.5	9.E	1.7.8	2.7.8	£.7.£	4.7.8	8.7.E	8.7.E		5.4		1.8 5.2 2.8		Surgical Procedures	FORA
o)(6), (b)(7)(c))(2)High & (b)(7)(F)	2007-1621	>	<u>≻</u>	≻	Rats	Avertin/perfusion A		<u> </u>	۲ ۲	۲	۷	۲ ۲	а.	≻				<u>≻</u>		· · · · · · · · · · · · · · · · · · ·		<	۷	۲	implant	Heliothane or gessereng system has r been used ye and is under construction. will put in plac prior to use o halothane.
																												No animals have been us on this protoc for over 6 months. La not inspected
		<u>_</u>	2006-1544 2006-1600	×	≻	≻	Rats	Pentobarb	Σ	4	-									╆┼┼	$\left \right $							
		_ <u> </u>	2007-1680	>																								Microsurgical anastamosis
		<u></u>						9 9		<u>≺</u>	<	w	۲			≻	z	z	<u>≻</u>	<u>≻ </u>				۷	۲	۷	Nonsurvival tissue harvest	
		· · ·					Mice												+								Stereostatic surgery (survival)	
										·		: i								·								3.4.5 Drugs 8 logs stored elsewhere
		.,	2007-1683	≻ ≻	≻	<u>≻</u>		Pentobarb/Exsan g	۲	A A	۷	S	۲			7	z	z	≻ ≻	≻ 、				4	۲	۲	Nonrecovery/tis sue harvest	
		•					Mice																				Sterotactic surgery (survival)	1.0. Survival surgery not listed on protocol summary
						·																						3.4.5. Drugs logs stored elsewhere
		<u> </u>	2005-1496	≻				Pentobarb/Exsan g	۲	¥	 		`	۲ ۲		≻	z	z	z z	≻				۲	۲	4	Non- recoveyr,trache ostomy,cannula	Add in the personnel- iula Amenda Knigl
		. 410	2007-1639		z	<u>></u> ;	Mice	CO2/Physical		A				\vdash	$\left - \right $	z	z	N			<u> </u>		-	◄	<u>ح</u>			f 24
		410	2007-1689	~				CO2/Physical	4	A					\square	z			z z	z				A	۲	A		11
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Principal Investigator				Use	of A	nimat	Use of Animals in Lab	Euthanasia Methods	uthanasia Methods Anesthesia and Surgery Time Animals	Anesthesia and Surgery	d Surg	ery			Time	Time Animals	-	Separating	bu		
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(b)		b)(2															-				10
)(6),		2)Hig	2006-1565																	5498 2 2	Nétanimals in use in lab
(b)(7		gh &	2006-1539					Iso/Cerv. A A Dislocation									<	4	A No surgery	5 C	Location need to be updated
')(c		(b)(2006-1546	γ	z	۲	Mice	Iso/Cerv. A A		_	≻ ≻	z	z		-				Implant, Islet		Lecatains nee
		(7)(F						Dislocation											recovering, only sacrifice in 4011	only to b 011	to be updated
)		_		_						1		_		_			WHW		
										-			+								
			2007-1616	z ≻	z	≻	Mice	Cerv. A A								-	4	4	A Protocol		
								Dislocation/Deca											inactive now but want to keen	put	
				+		_								_					open		
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				z ≻	z	۲	Mice	Exsan/cerv Disl	X X	X	z z	z	z		-		<	A	A None	EXP (A)	oired xylazi
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				+	-																
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			2007-1656	N Y	z	N Mice		Cervical Dislocation	A A	۲														-			
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			2007-1640	z		Rats		Decapitation	4	A				_	+	_					-						
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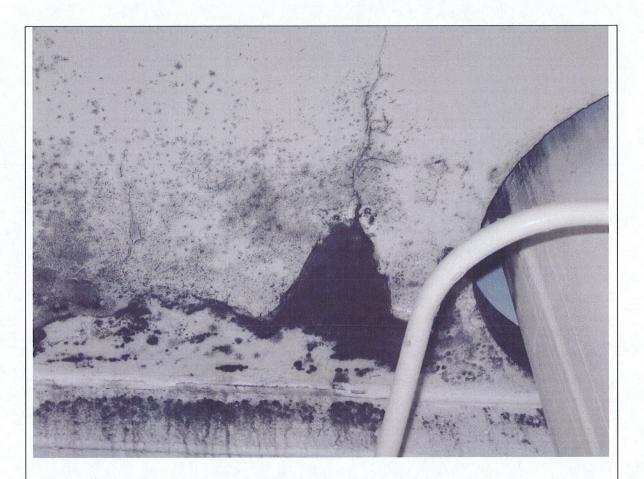
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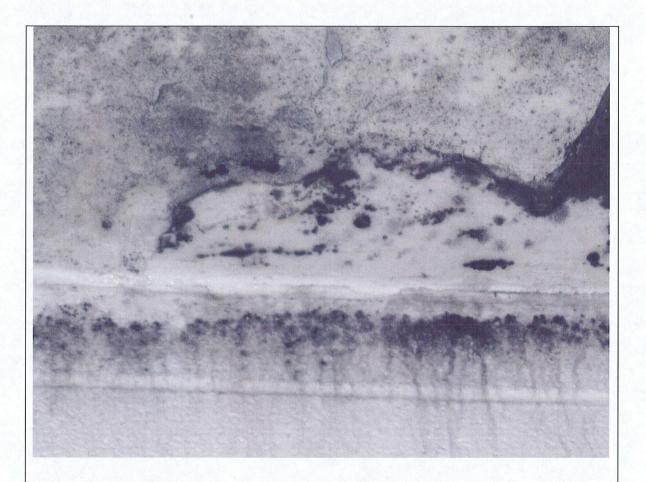
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SUBJECT NAME:	University of Kansas Medical Center
LICENSE/REGISTRATION #:	48-R-003
9 CFR SECTION #:	3.56 (c) Sanitation
DESCRIPTION:	The ceiling in this room used to house rabbits has a black, mold like substance.
DATE:	August 27, 2008
TIME:	
PHOTOGRAPHER:	Katheryn Ziegerer, VMO



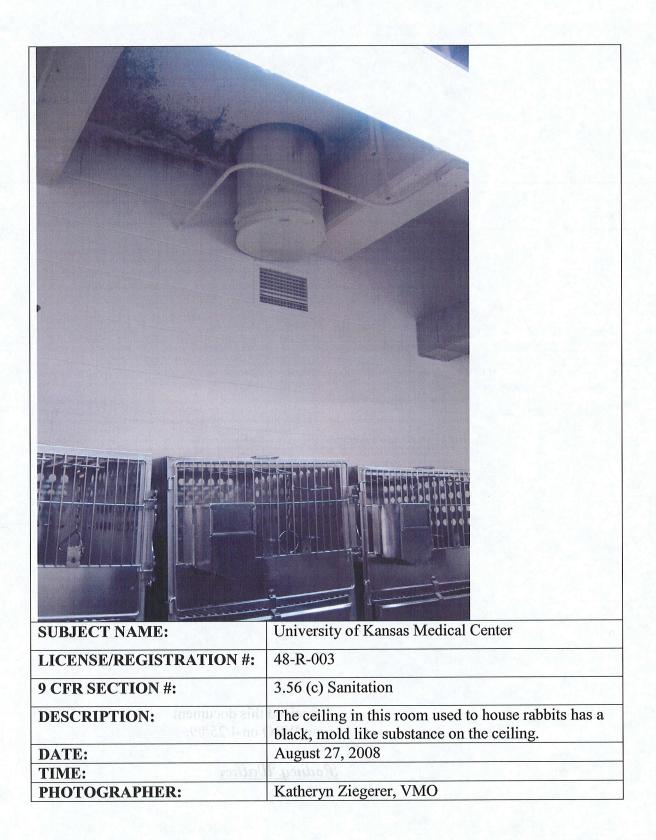


SUBJECT NAME:	University of Kansas Medical Center
LICENSE/REGISTRATION #:	48-R-003
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PHOTOGRAPHER:	Katheryn Ziegerer, VMO

from WRO on 4/25/04

Rodney Walker









SUBJECT NAME:	University of Kansas Medical Center
LICENSE/REGISTRATION #:	48-R-003
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PHOTOGRAPHER:	Katheryn Ziegerer, VMO

from WRO on 4/25/0

Radney Walke



SUBJECT NAME:	University of Kansas Medical Center
LICENSE/REGISTRATION #:	48-R-003
9 CFR SECTION #:	3.56 (c) Sanitation
DESCRIPTION:	The ceiling in this room used to house rabbits has a black, mold like substance.
DATE:	August 27, 2008
TIME:	
PHOTOGRAPHER:	Katheryn Ziegerer, VMO

I received this document

GOVERNMENT	
Page of APHIS FORM 7070 (MAR 95)	

SUBJECT NAME:	University of Kansas Medical Center
LICENSE/REGISTRATION #:	48-R-003
9 CFR SECTION #:	3.56 (c) Sanitation
DESCRIPTION:	The ceiling in this room used to house rabbits pealing paint.
DATE:	August 27, 2008
TIME:	
PHOTOGRAPHER:	Katheryn Ziegerer, VMO

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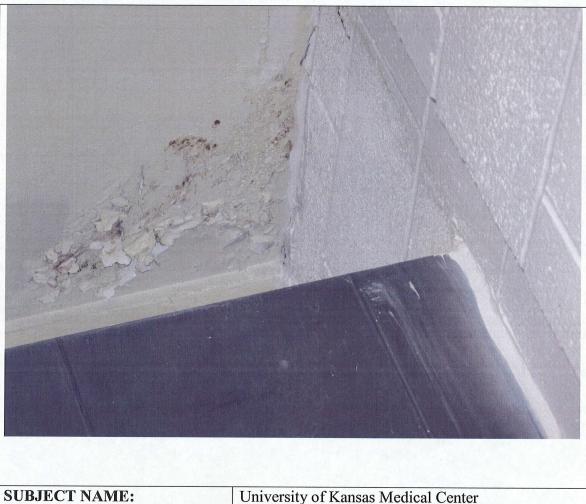


SUBJECT NAME:	University of Kansas Medical Center
LICENSE/REGISTRATION #:	48-R-003
9 CFR SECTION #:	3.56 (c) Sanitation
DESCRIPTION:	The ceiling in this room used to house rabbits has a black, mold like substance and pealing paint.
DATE:	August 27, 2008
TIME:	
PHOTOGRAPHER:	Katheryn Ziegerer, VMO

from WRO on 4/25/0

Rodney Walko





SUBJECT NAME:	University of Kansas Medical Center
LICENSE/REGISTRATION #:	48-R-003
9 CFR SECTION #:	3.75 (a) General housing facilities
DESCRIPTION:	The paint is pealing on the ceiling in a room used to house non-human primates.
DATE:	August 27, 2008
TIME:	Radaeu
PHOTOGRAPHER:	Katheryn Ziegerer, VMO





SUBJECT NAME:	University of Kansas Medical Center
LICENSE/REGISTRATION #:	48-R-003
9 CFR SECTION #:	3.75 (a) General housing facilities
DESCRIPTION:	The paint is pealing on the ceiling in a room used to house non-human primates.
DATE:	August 27, 2008
TIME:	
PHOTOGRAPHER:	Katheryn Ziegerer, VMO

Radney Walker





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LICENSE/REGISTRATION #:	48-R-003
9 CFR SECTION #:	3.75 (a) General housing facilities
DESCRIPTION:	The paint is pealing on the ceiling in a room used to house non-human primates.
DATE:	August 27, 2008
TIME:	
PHOTOGRAPHER:	Katheryn Ziegerer, VMO

from WRO on 4/25/0

Rodney Walker



SUBJECT NAME:	University of Kansas Medical Center
LICENSE/REGISTRATION #:	48-R-003
9 CFR SECTION #:	3.75 (c) (1) Housing facilities general
DESCRIPTION:	The wall in this room used to house non-human

DESCRIPTION:	The wall in this room used to house non-human primates is damaged to the point that materials that are not impervious to moisture are exposed.
DATE:	August 27, 2008
TIME:	
PHOTOGRAPHER:	Katheryn Ziegerer, VMO
Lthis document O on 4/25/09,	

GOVERNMENT EXHIBIT Page___ot__3_ APHIS FORM 7070 (MAR 95)



SUBJECT NAME:	University of Kansas Medical Center
LICENSE/REGISTRATION #:	48-R-003
9 CFR SECTION #:	3.75 (c) (1) Housing facilities general
DESCRIPTION:	The wall in this room used to house non-human primates is damaged to the point that materials that are not impervious to moisture are exposed.
DATE:	August 27, 2008
TIME:	
PHOTOGRAPHER:	Katheryn Ziegerer, VMO

Radney Walker





SUBJECT NAME:	University of Kansas Medical Center
LICENSE/REGISTRATION #:	48-R-003
9 CFR SECTION #:	3.75 (c) (1) Housing facilities general
DESCRIPTION:	The wall in this room used to house non-human primates is damaged to the point that materials that are not impervious to moisture are exposed.
DATE:	August 27, 2008
TIME:	
PHOTOGRAPHER:	Katheryn Ziegerer, VMO



SUBJECT NAME:	University of Kansas Medical Center
SUBJECT NAME: LICENSE/REGISTRATION #:	University of Kansas Medical Center 48-R-003
LICENSE/REGISTRATION #: 9 CFR SECTION #: DESCRIPTION:	 48-R-003 3.75 (f) General housing facilities This refrigerator is being used to store necropsy samples and medications. Note the spilled liquids present within the refrigerator.
LICENSE/REGISTRATION #: 9 CFR SECTION #: DESCRIPTION:	 48-R-003 3.75 (f) General housing facilities This refrigerator is being used to store necropsy samples and medications. Note the spilled liquids

GOVERNMENT EXHIBIT) 2 Page_1_of_5 APHIS FORM 7070 (MAR 95)

SUBJECT NAME: LICENSE/REGISTRATION #:	University of Kansas Medical Center 48-R-003
9 CFR SECTION #:	3.75 (f) General housing facilities
DESCRIPTION:	This refrigerator is being used to store necropsy samples and medications. Note the spilled liquids present within the refrigerator.
DATE:	August 27, 2008
TIME:	
PHOTOGRAPHER:	Katheryn Ziegerer, VMO

GOVERNMENT EXHIBIT / 2 Page 2 of 5 APHIS FORM 7070 (MAR 95)

<image/>	
SUBJECT NAME: LICENSE/REGISTRATION #:	University of Kansas Medical Center 48-R-003
9 CFR SECTION #:	3.75 (f) General housing facilities
DESCRIPTION: 10000000000	This refrigerator is being used to store animal parts
0 00 4/25/09.	and medications. Note the skull cap from a non-
DATE	human primate next to the medication.
DATE:	August 27, 2008
TIME:	Katheryn Ziegerer, VMO
PHOTOGRAPHER:	Kainervn Ziegerer, VIVIO

GOVERNMENT EXHIBIT / 2 Page______of_____ APHIS FORM 7070 (MAR 95)

SUBJECT NAME:	University of Kansas Medical Center
LICENSE/REGISTRATION #:	48-R-003
LICENSE/REGISTRATION #: 9 CFR SECTION #:	48-R-0033.75 (f) General housing facilities
LICENSE/REGISTRATION #:	 48-R-003 3.75 (f) General housing facilities This refrigerator, used to store medications and food items for the non-human primates, has a brownish
LICENSE/REGISTRATION #: 9 CFR SECTION #: DESCRIPTION: DATE:	48-R-0033.75 (f) General housing facilitiesThis refrigerator, used to store medications and food
LICENSE/REGISTRATION #: 9 CFR SECTION #: DESCRIPTION:	 48-R-003 3.75 (f) General housing facilities This refrigerator, used to store medications and food items for the non-human primates, has a brownish liquid material on its shelves and the door.

GOVERNMENT EXHIBIT / 2_ Page 4 of 5 APHIS FORM 7070 (MAR 95)



SUBJECT NAME:	University of Kansas Medical Center
LICENSE/REGISTRATION #:	48-R-003
9 CFR SECTION #:	3.75 (f) General housing facilities
DESCRIPTION:	These medications were present in the refrigerator being used to store necropsy samples and animal parts.
DATE:	August 27, 2008
TIME:	
PHOTOGRAPHER:	Katheryn Ziegerer, VMO



Il redactions on this page are pursuant to (b)(6) & (b)(7)(c).



United States Department of Agriculture Animal and Plant Health Inspection Service

INSPECTION REPORT

192 of 241

Customer #: 1460 Certificate #: 48-R-0003

Site #: 001

UNIVERSITY OF KANSAS MEDICAL CENTER

3901 Rainbow Blvd. 1040 Wescoe Pavilion-MS 2014 Kansas City, KS 66160 Site Name: UNIVERSITY OF KS MED CTR

INSPECTION Type: ROUTINE Date: DEC-18-2008

NARRATIVE

2.36 (b) (3) ANNUAL REPORT

(b) The annual report shall:

(3) Assure that the facility is adhering to the standards and regulations under the Act, and that it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such exceptions must be attached to the facility's annual report. In addition to identifying the IACUC-approved exceptions, this summary must include a brief explanation of the exceptions, as well as the species and number of animals affected;

The annual report submitted by the institution did not include notification of any exemptions to the Animal Welfare Act standards and regulations approved by the IACUC. During the reporting period, the IACUC approved at least two exemptions:

 A male macaque was housed in a cage that did not allow him to stand up straight.
 A non-human primate protocol required that animals be exempted from the institution's standard enrichment program due to concerns that the enrichment would interfere with the protocol's results.

All exemptions to Animal Welfare Act standards and regulations must be reported to the Animal Care Regional Director in order to protect the health and welfare of the animals. This report must be included with the annual report and include a brief explanation of the exceptions as well as the species and number of animals affected. The institution must submit an amended annual report including a summary of the exceptions to the Regional Office.

TO BE CORRECTED BY: January 9, 2009

Althe Arizan Min	
Prepared by: Katheryn Ziegerer, V.M.O. Title: Veterinary Medical Officer, USDA, APHIS, Animal Care	Date: DEC-18-2008 Inspector ID: 5052
	Date: DEC-18-20
Page 1 of 2	8007



All redactions on this page are pursuant to (b)(6) & (b)(7)(c). United States Department of Agriculture Animal and Plant Health Inspection Service

193 of 241

INSPECTION REPORT

Customer #: 1460 Certificate #: 48-R-0003

Site #: 001

This was a focused inspection, only examining annual report compliance. This inspection was conducted by Katheryn Ziegerer, VMO, and facilities representatives. An exit conference was conducted at the time of the inspection.

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Prepared by: Katheryn Ziegerer, V.M.O. Title: Veterinary Medical Officer USDA APHIS, Animal Care

Date: DEC-18-2008 Inspector ID: 5052

Received by: Title: of Office of Compliance Date: DEC-18-2



Page 2 of 2

result in an order to ce	ase and desist and to be subje	to report according to the re act to penaltie: a povided to	egulations can for in Section 21?		See attached form for additional mation.	Interagency Report Control No .:
UI FOIAN	NITED STATES DEPARTN 104548ND PLANT HEALT	MENT OF AGRICULTUR H INSPECTION SERVIC	RE CE		FICATE NUMBER: 48-R-0003 FOMER NUMBER: 1460	194 5051 APPROVED OMB NO. 0579-0036
	UAL REPORT OF (TYPE OF Y (List all locations where an	R PRINT)	:	3901 I 1040 \ Kansa Teleph	rsity Of Kansas Medical Center Rainbow Blvd Wescoe Pavilion - Ms 2014 Is City, KS 66160 none: (913) -588-7015	sheets if necessary)
• •		FAC	LITY LOCATIONS (S	ites) - See	Atached Listing	
REPORT OF ANIMA	LS USED BY OR UNDER	CONTROL OF RESEAU	RCH FACILITY (Attac	ch addition	al sheets if necessarv or use APHIS Form 70)23A)
A. Animals Covered By The Animal Welfare Regulations	B. Number of animat being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animy which experimer teaching, resear surgery, or tests conducted involv accompanying p distress to the ar for which approp anesthetic, analg tranquilizing drug used.	als upon nts, ch, were ring ain or nimals an riate esic, or	E. Number of animals upon which teaching, expresearch, surgery or tests were conducted invaccompanying pain or distress to the animals the use of appropriate anesthetic, analgesic, or drugs would have adversely affected the proce or interpretation of the teaching, research, exp surgery, or tests. (An explanation of the proce producing pain or distress in these animals an such drugs were not used must be attached to be added to be a	eriments, olving and for wh or franquiliz edures, res eriments, edures d the rease COLUMNS
4. Dogs	3	0	14	· · · · · · · · · · · · ·	0	14
5. Cats	0	0	D		0	0
. Guinea Pigs	0	14	()			110
. Hamsters	0	20	57	0	\mathcal{D}	7
. Rabbits	0	20	13	5	<u>_</u>	115
. Non-human Primates	0	5	153		AN LOW A	150
). Sheep	0	0	D		0	
: Pigs	0	0	58	3	0	58
. Other Farm Animals						
GOG TS Other Animals	0	0	5	:	0	
Gerbils	0	0	48		0	48
			· ·			
SSURANCE STATEMENT	s			l		
 Each principal investi This facility is adherin Institutional Animal C brief explanation of th The attending vetering 	gator has considered alternativ ng to the standards and regulat are and Use Committee (IACU) e exceptions, as well as the sp	ves to painful procedures. ions under the Act, and it ha C). A summary of all such ecles and number of anima as appropriate authority to o CERTIFICATION BY I	as required that exception exceptions is attached is affected. ensure the provision of ac	is to the stand to this annu- lequate veter SEARCH F nsible Institu	Inestetic, analgesic, and tranquilizing drugs, prior to, or dards and regulations be specified and explained by the al report. In addition to identifying the IACUC-approve inary care and to oversee the adequacy of other aspe- ACILITY OFFICIAL utional Official)	19 classical and an
H	יטן טביטו ואורט ו טי שטעוקאר	or oo, which is obsolute.				11/12/08







University of Kansas Medical Center Institutional Animal Care and Use Committee

Minutes

- DATE: May 20, 2008
- TIME: 8:30 AM
- PLACE: 2001 LAR

1.0 Members present at this meeting (for secretary use only)

Name 👘	Department / Affiliation	Location	Status	Attendance
(b)(6), (b)(7)(c)	Hearing & Speech	(b)(2)High & (b)(7)(F)	Voting member	Present
	Community Member		Non-Aff	Present
	LAR		Voting member	Present
	Env. Health & Safety		Voting member	Present
	Office of Compliance		Non-voting support	Present
	Office of Compliance		Non-voting support	Present
	Office of Compliance		Non-voting support	Present
	Biochemistry		Voting member	Present
	OB/GYN		Vice Chair	Present
	Hem/Onc		Voting member	Absent
	Anatomy		Voting member	Present
	LAR		Voting member	Present
	Physiology		Voting member	Present
	School of Nursing		Voting member	Present
	Occ. Therapy		Voting member	Present
	Physiology		Voting member	Present
	Pastoral Care		Voting member	Present
	Anatomy		Chair	Present
	Thrp Disc & Dev		Voting member	Present
	Microbiology		Voting member	Present
	Biostatistics		Voting member	Present

- 2.0 Approval of minutes of the previous meeting
 - 2.1 Meeting Date: April 14, 2008
 - 2.2 Status: Approved
 - 2.3 Comments:



FOIA 10-549 New Proposals 3.0

	Department			
2008-1728	(b)(6), (b)(7)(c) OB/GYN	1200 MICE USDA B	MicroRNA regulation of development and function of the female reproductive tract	Approved w/contingencies

The IACUC reviewed the above referenced animal care and use proposal (ACUP). It was approved with the following contingencies.

Form Item 6.1. Please list the number of animals in table format for Experiment #2 in both Aims as was done in Experiment #1. An inconsistency is noted of sample size in this proposal. It is stated that the sample size N = 16for Aim#1 Experiment#2 (p.8, Line 6) but had N = 13 in this sample size justification "For these studies, we anticipate that we will require 13 mice/day ...". When I checked his justification, he assumed 6 pups/liter for the control group and 66% reduction in the experimental group (i.e. 3 pups/liter) and standard deviation (SD) of 6. However, if he expects the average to be 3 pups/liter for the experimental group, SD = 6 implies > 30% chance of negative number of pups under normal distributions. Then the justification based on 2-sample t-test is not valid. The strict justification is a challenge. To make an easy (quick but dirty) valid justification, we suggest Dr. (b)(6), (b)(7)(c_{assume} a smaller SD, say SD = 3, for the experimental group so that the chance of having a negative number of pups is about 7% (not very close to 0 though, much better than 30%) and SD = 6 remains the same for the control group. In this way, staying with N = 13 mice per group will provide more than 80% power, and he does not need to change the total number of animals. Form Item 6.4.3. Please complete this section.

Form Item 6.5. Please complete this section.

Please complete an IRSC form.

4.0 **Re-submissions - None**

Protocol# Principal Investigators Department	Species The Third States and Stat	Status
	USDA Class	
		Approval Contingencies
		Tabled Disapproval





5.0 FOLA 10-549 De novo re-writes

2008-1733 (b)(6), (b)(7)(c)	eator Species A. Mumber M. Fequested USDIA Class		
Molecular & Inte	grative 7 PRIMATES	Electrical stimulation of cortical motor output	Approved
Physiology	USDA C		w/contingencies

The IACUC reviewed the above referenced animal care and use proposal (ACUP). It was approved with the following contingencies.

Form Item 1.1. In "ACUP Summary Data", please change the euthanasia method to "ketamine in combination with metatomadine" plus add a physical method (exsanguination).

Form Item 2.0. Please include protocol number of protocol being replaced.

Form item 4.0. Please add a statement indicating why less sentient vertebrates would be inappropriate.

Form Item 6.1. Please provide a description of the procedure used to acquire EMG potentials (e.g., how are the monkeys connected to the instrumentation)? Under "study group 2", in the first paragraph, the committee assumes "aims 1-5" should be "aims 1-4". Likewise in the justification paragraph, "aims 2-4" should be "aims 1-4". Please clarify.

Form Item 6.3. If sutures are used to close the scalp incision, a discussion of suture inspection and removal should be included. If they (or an equivalent) are not used, please state how the scalp wound is closed?

Form Item 6.4. Monkey collars are described as including an activity monitor, but the purpose of this monitor is not explained. Please address.

Form item 6.3.5. The veterinary staff suggested that antibiotics be started before surgery.

Form Item 6.4.2. Please provide additional information regarding the behavioral training procedures. For instance, duration of training (per session, total sessions), adaptation to primate chair and task requirements, type of task feedback provided, etc., to provide the committee with insight into the potential stress associated with such experiences.

Form Item 6.4.3. Most of the answer given here relates to post-surgical pain/distress and should be moved to section 6.3.5. Instead, please elaborate on any potential pain/distress issues related to non-surgical procedures. Form Item 6.5. Please add information regarding potential post-op conditions that might warrant euthanasia. Form Item 6.6. Please add isoflurane to the table.

Form Item 6.7. Clarify whether the behavior work is being done in the RSF (as written) or in Smith East. Clarify whether monkeys will be working on the tasks for 40-60 minutes (as suggested here) or for 2-4 hours (as suggested in section 6.4.2). Under "other aspects", please describe the primate jackets and their care. Include a justification for their use and the length of time animals are restrained in jackets. In either "other aspects" or in section 6.4.3, please address the adaptation of the monkeys to head restraint procedures after the weeks/months of behavioral training without head restraint.

Form Item 6.10. For Dr. ^{(b)(6), (b)(7)} please list specific duties other than just "PI" (e.g., surgery). Also, please add Dr. ^{(b)(6), (b)} to this list.

Form Item 11.0. The housing location should be the 5th floor of Smith East.

2008-1731	(b)(6), (b)(7)(C)	207 MICE	alman	
2000 1751		397 MICE	C/EBPB in PKD pathogenesis	Approved
]	a contra marka paulogenesis	Approved
	Pharm/Tox/Thrp	USDA C	and your al ("I.	w/o anti-
		IUDDAC	and renal fibrosis	w/contingencies
ThatACHIC	1.1 1 0			0

The IACUC reviewed the above referenced animal care and use proposal (ACUP). It was approved with the following contingencies.

Form Item 1.1. In summary table, list all procedures used on animals in protocol including tissue harvest, tail clips, toe clips, etc.

Form Item 3.0. The concordant review in item 12.0 does not describe UUO experiments. In addition, mention of the purpose of this project is to obtain preliminary data, in section 6.1, suggests that these experiments is the purpose of the purpose

been peer reviewed. Explain how this protocol has been completely peer-reviewed, or have chairman sign off as not peer-reviewed.

Form Item 6.1. Please clarify what is meant by "identify >100% difference in renal injury". In power analysis for study 1-1, indicate what "means" are being used. In study 1-2, provide age of mice for cell culture and justification for the numbers of mice required. For example, # IMCD cells expected to be generated from kidney pairs and how many cell numbers are needed for each measurement (cell proliferation, apoptosis, cyst formation, fluid secretion, and gene expression). Explain how the mice for cell culture will be generated. In the introduction for Aim #2, define the abbreviation. Please correct "day 8" in table. Correct number of mice needed for cell culture experiments by including second age. Study 2-2 describes that 4 mice/group will be used, yet 6 mice are listed per study 2-2. Veterinarians suggest that UUO model is not good renal fibrosis model and suggest use of low amount of ethylene glycol.

Form Item 6.2. Please provide a table indicating the predicted number of all genotypes from the crosses and indicate the animals that will be used in the studies and those that will be culled. Study 2 -1 says that two ages of mice will be used for cell culture, yet table only lists mice for one age. In addition, ham operated controls and ROSA26 mice do not appear in animal numbers table. Please be sure to include animal numbers for second age in study 2-1, for sham operation controls for study 2-2 and for ROSA26 mice. Some of the mice for studies 1-1 and 1-2 are included in USDA category E. Please provide justification for the need to use mice in this category. Form Item 6.3.3. Please correct table. Three different anesthesia agents are listed, yet only one is described as being used.

Form Item 6.3.4. Vascular cannulations are listed in the table, but not in the study design, please clarify. Sham operation controls are mentioned but no mice are allotted for this control. LAR vets recommend that UUO mice be placed in category E and justified unless pain relief will be provided for the two weeks of the experiment. Please correct table and place UUO mice in category E or explain why they should not be in category E. Form Item 6.4. Describe when and why retro-orbital bleeds are being performed. Also, indicate if procedure will be performed with analgesia or under anesthesia. If not, provide justification.

Form Item 6.4.3. The deletion of C/EBP beta from bone may result in deleterious effects, please discuss the potential effects and plans for pain/distress. Also describe how pain will be managed. Form Item 6.10. Please provide assurance that ^{(b)(6), (b)(7)(c)} is trained to perform peopetal LULO surgerise.

Form Item 6.10. Please provide assurance that $\binom{(b)(6), (b)(7)(c)}{(b)(7)(c)}$ is trained to perform neonatal UUO surgeries.

Form Item 8.0 Please identify nothegonic cell lines or materials.

(b)(6), (b)(7)(c)	ton materials.			
	577 MICE USDA C	C/EBPbeta in liver pathophysiology and carcinogenesis	Approved w/contingencies	

The IACUC reviewed the above referenced animal care and use proposal (ACUP). It was approved with the following contingencies.

Please define all abbreviations and/or acronyms the first time used.

Form Item 1.0. Animal use location has LAR and KLSIC 4001. Please check with veterinary staff and confirm if infected animals will be allowed in KLSIC. Please add LVS (Live Vaccine Strain) following *Franciscella*

Form Item 1.2. Please update animal training date to most recent refresher training date.

Form Item 3.0. Please clarify that the renal fibrosis study is not peer reviewed.

Form Item 4.0. Aim 1 does not seem to reflect some of the studies being done in the protocol. There is no mention of the liver cancer studies. Please list the aims in this section as stated later in the protocol under sections 1-1, 1-2, 1-3, 1-4 and 1-5. This would make five specific aims and improve the clarity under 4.0.

Form item 5.3. Please modify search to include results from PubMed or Medline in addition to the research and animal welfare databases listed.

Form Item 6.1. Under study 1-4, as stated this is a liver fibrosis and carcinogenesis study for which the animals will be sacrificed at 3, 9 and 15 months. In almost all carcinogenesis studies the animals are under some states and the sacrificed at 3, 9 and 15 months.



pain and distress from tumor burden. It would appear the animals in study 1-4 should be placed in category D (if pain and distress are to be relieved) or E (if pain and distress are not to be alleviated). If the investigator wishes that the animals remain in category C then please describe why they believe the tumor burden animals will not be under pain and distress. Similar studies in this protocol under aim 1-5 have tumor burden animals in category D. Regarding the intrahepatic infection with *Francisella tularensis*, the ACUP states Dr. ^{(b)(6), (b)(7)(c)} will conduct the infected animals be housed for the 2 or 6 days after inoculation?

Form Item 6.2. Please state your plans for the extra offspring from breeders and are these taken into account in the animal number estimates? There are 20 + 12 animals in Category E – but there is no accompanying justification for these animals. There needs to be a clearly identified section of texts that addressed the need for Category E specifically.

Form item 6.3.2. Please note that buprenex will be given pre-operatively.

Form Item 6.3.4. Please add that the animal will be scrubbed first with betadine followed by 70% ethanol three times around the surgical site to create a sterile field. Additionally, the reference (Wang et all 2006) listed in the ACUP describes an intrasplenic/portal injection in the methods section suggesting a specific anatomical location in the spleen that may be critical to the dissemination of metastasis. Please clarify if there is a specific inoculation site in the spleen such that after a one minute incubation followed by splenectomy it will allow for the development of liver metastasis. Also, please indicate the experience of the investigator performing these procedures and whether they have successfully achieved liver metastasis using this model. Please state if bile duct ligation leads to pain/distress after 2 weeks.

Form Item 6.3.5. Please state if post-operative pain may persist and if so, indicate the length of time. Form item 6.4. Please provide more information about toe clips and retro orbital bleeds. Please provide justification for the need to use this method of identification, indicate the age at which animals will undergo toe clips, if this will be done under anesthesia or with an analgesic. If not, provide justification for withholding.

Also, indicate the frequency of retro orbital bleeds, if the procedure will be done under anesthesia or with an analgesic. In addition, indicate if the procedure will be done on alternating eyes if frequent.

Form Item 6.4.2. Please add the cardiac bleed described under 9.0 in this section. Please mention injections of agents here, even though they are detailed earlier.

Form Item 6.4.3. Please add your pain management plan specifically for Category E animals, in addition to the listed clinical signs of pain and distress. If pain and distress are to be untreated please indicate.

Form Item 6.5. Please define "persist". Please indicate the period in time in which a >15% weight change in mice will be observed. Also, when will baseline weight be obtained?

Form Item 6.8. Please indicate physical methods for pentobarbital and CO2.

			l l
(b)(6), (b)(7)(c)	198 MICE	Immune tolerance in pregnancy App	roved
	USDA B		ontingencies
	627 MICE		-
	USDA C		
IACUC reviewed the abarra	C. 1 1 1 1		

The IACUC reviewed the above referenced animal care and use proposal (ACUP). It was approved with the following contingencies.

Define all abbreviations and acronyms the first time used.

Form item 1.2 and 6.10. Please confirm spelling ^{(b)(6), (b)(7)(c)} and list consistently in both tables.

Form Item 4.0. Specific Aim I: Please define the Act-mOVA mice, and provide rationale for their use. Specific Aim II: Please define OT-I mice and describe how they will be used.

Form item 6.0. Aim 1, exp 1, please justify using 4 mice/sample by estimating the number of cells needed and the number of cells that can be obtained per mouse. Also, the protocol implies that it will take 28 females to ensure four females at a time are plugged. 28 females x 3 time points x 4 replicates x 2 male strains = 672 females. Please clarify why 135 females are requested.

Form Item 6.4.3. To avoid confusion regarding euthanasia technique, indicate that euthanasia by CO2 inhalation will be followed by cervical dislocation.



All redactions on this page are pursuant to (b)(6) & (b)(7)(c).

376 PIG USDA DDilation of pig arteries a veins by proteolysis of intramural elastinThe IACUC reviewed the above referenced animal care and use proposal (ACUP). It was following contingencies.Dilation of pig arteries a veins by proteolysis of intramural elastinForm Item 1.0. Please provide the summary missing on the first page.Form item 4.0 and 5.3 (replacement). Please indicate why the pig is the most appropriate rest sentient model is not suitable.Form Item 5.3. Please clarify why a 10% loss of animals is expected.Form item 6.2. The committee believes that the number of pigs requested is high especiall work is complete. Please provide justification for animal numbers requested.Form Item 6.9. Please enter the physical method of euthanasia used in conjunction with be Form Item 6.3.4. Please clarify which animals will undergo which procedures and start			
USDA D USDA D The IACUC reviewed the above referenced animal care and use proposal (ACUP). It was following contingencies. Form Item 1.0. Please provide the summary missing on the first page. Form item 4.0 and 5.3 (replacement). Please indicate why the pig is the most appropriate re- sentient model is not suitable. Form Item 5.3. Please clarify why a 10% loss of animals is expected. Form item 6.2. The committee believes that the number of pigs requested is high especiall work is complete. Please provide justification for animal numbers requested. Form Item 6.9. Please enter the physical method of euthanasia used in conjunction with be Form Item 6.3.4. Please clarify which animals will undergo which proceedings and starts of the physical method of euthanasia used in conjunction with be	200 of 241		FOIA 10-549 376 PIG
The IACUC reviewed the above referenced animal care and use proposal (ACUP). It was following contingencies. Form Item 1.0. Please provide the summary missing on the first page. Form item 4.0 and 5.3 (replacement). Please indicate why the pig is the most appropriate resentient model is not suitable. Form Item 5.3. Please clarify why a 10% loss of animals is expected. Form item 6.2. The committee believes that the number of pigs requested is high especiall work is complete. Please provide justification for animal numbers requested. Form Item 6.9. Please enter the physical method of euthanasia used in conjunction with be Form Item 6.3.4. Please clarify which animals will undergo which proceedings and start and	s and Approved	filation of pig arteries and Approved	
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this percentage will be over an extended period of time. Form item 6.6. Please include contrast agents in this list.	e model and why a less ally since most of this beuthanasia.	pposal (ACUP). It was approved with the ge. s the most appropriate model and why a less d. uested is high especially since most of this requested. in conjunction with beuthanasia.	Form Item 1.0. Please provide the summary missing on the fin Form item 4.0 and 5.3 (replacement). Please indicate why the sentient model is not suitable. Form Item 5.3. Please clarify why a 10% loss of animals is ex Form item 6.2. The committee believes that the number of pig work is complete. Please provide justification for animal num Form Item 6.9. Please enter the physical method of euthanasia Form Item 6.3.4. Please clarify which animals will undergo will Form item 6.5. The committee believes that greater than 30% this percentage will be over an extended period of time

6.0 Proposals Requiring Investigator Action

Protocol#	Principal Investigator Department	Species	Dule 2	a status a
		MICE	Type IV Collagen, Laminins, and Integrins Regulate Glomerular Formation/Function	Approved
		MICE	Delivery of chemotherapeutics to the lymphatic system for treatment of cancer	Approved
		RATS	Oxidant Stress-induced Liver Injury	Pending Response from PI
		MICE	Mechanisms of Microcystin- induced Liver Injury	Pending Response from PI
		MICE	Regulation of hepatic uptake and efflux transporters	Approved
		MICE	Role of Abcb6 in drug metabolism and disposition in liver	Approved
		PRIMATES	Use of the Vpu Inhibitor BIT225 to Control SHIV Replication	Pending Response from PI
		MICE	Thymic Migration Studies	Approved



All redactions on this page are pursuant to (b)(6) & (b)(7)(c).

7.0 FAIA 10-549 Addenda reviewed in meeting

Protocol#Principal-Investigator	Species	Title	Status /
	MICE, RATS	Traumatic Central Nervous System Injury: Mechanism of outcome based on age and hormone status	Tabled
The IACUC reviewed and tabled the adder is a list of items to address in the re-write.	ndum to the above ref	erenced animal care and use propo	sal. Following

Please remove references to and her protocol (2006-1550) from ACUP identification section. Form Item 1.0. Please describe the proposed procedures, animals needs associated with those procedures, rationale for change, and indicate study personnel responsible for them.

Form Item 3.0. This requires an answer as to how the changes are different from existing protocol.

Form Item 5.0. Please add information about animals being used. Include the number of animals requested, USDA class and statistical justification

MICE, RATS	Synthesis & Testing of Male Contraceptive Agents	Tabled

The IACUC reviewed and tabled the addendum to the above referenced animal care and use proposal. Following is a list of items to address in the re-write.

Form Item 1.0. Please describe the proposed procedures, animal needs associated with those procedures, and rationale for changes.

Form item 3.0. Describe how this relates to and differs from existing protocol.

Form Item 5.1. Indicate how many animals will be needed in each USDA class. Then provide statistical justification for the number of animals requested. If its not possible to obtain statistical justification, estimate need based on citation of previous work, or anticipated cell yields multiplied by the number of animals required to obtain that yield then the number of replicates for each experiment.

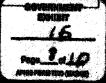
8.0 Addenda reviewed outside meeting

Protocol # Principal Investigator Department	Species	Title	Status
	MICE, RATS	Molecular physiology of the NA, K-ATPase isoforms	Approved
	PRIMATES	Morphine And the Neuropathogenesis of SIV in Macaques	Approved
	PRIMATES, RATS	Nanoparticle-Based Gene Therapy for SHIV-Pneumonia in Macaques	Approved
	RATS	Metabolic Physiology in Rodents	Approved
	MICE	Role of coagulation in tissue injury	Pending R sponse sector

All reda	ctions on this page are pursuant to (b)(6) & (b)(7)(c).	
FOIA 10-54 <mark>9</mark>		2	02 of 241
	MICE	Humanized prostate cancer	Approved
		tumor models	
	MICE	Antibody Induction by an	Approved
		Antigen in Two Different	
		Forms	

9.0 Proposals under annual review

Protocol# Principal Investigator Department		Tul	STRUS
	MICE	Mineralization Studies Related to Oral Biology	Approved
	MICE	Development of magnetic resonance spectroscopy (MRS) studies of small aniamls at 9.4 T	Approved
	MICE	Nrf2-ARE Pathways: Discovery of Novel Chemopreventive Compounds	Approved
	RATS	Brain LC-PUFAs and Maternal Mental Health	Approved
	MICE	Eicosanoids in glomerular permeability	Approved
	MICE	Innate Immunity to Francisella tularensis	Approved
	MICE	Locus-linked Regulatory Motifs of Globin Gene Switching	Pending Response from PI
	RATS	Contributing factors in an animal model of retinophathy of prematurity (ROP)	Approved
	MICE	Viral fitness within hosts: Theory in a novel experiment system	Pending Response from PI
	RATS	NGT	Approved
	MICE	Chemokine Regulation of Breast Cancer Metastasis	Approved
	MICE	Morphine regulates Th1/Th2 CD4+ T cell differentiation	Approved
			SOVERNMENT-



All redactions on th	is page are pursuant to (b)(6) & (b)(7)(c).	
2007-F840 ¹⁰⁻⁵⁴⁹ Pharm/Tox/Thrp	RATS	The Suppresive Effect of Tryptophan Metabolites on the Immune Rejection of Rat Cardiac Transplants	3 of 241 Approved

10.0 Requests for deactivation

Protocol #:	PrincipaLinvesti Department	uago: Species	Title	Status
2005-1500		MICE	Regulation and function of Egr in gonadotropes	Approved
2005-1492		MICE	Src Tyrosine Kinase Regulates Gonadal Steroidogenesis	Approved

11.0 Programmatic exemptions

- 11.1 Cheney protocol # 2005-1507 due to difficulty with operating the PI's pole and collar system to remove primates from 2-plex cages, the PI has requested approval to temporarily keep a primate in a 4-plex cage that is slightly smaller than optimal until modifications can be made to the pole and collar system that will work better with 2-plex cages. The 4-plex cage meets weight but not height requirements.
- **11.2** Klaasen protocol 2005-1504 . The investigator requests extending the weaning date for CAR-null mice to postnatal days 24-25.

Smith, Marilyn 2006-1560. The investigator requests permission to extend the weaning age of newborn NOD/scid IL2R gamma null mice to 28 days to increase survival rates.

- 11.3 Soares protocol 2007-1645. The investigator requests to extend the weaning age of mice to 28 days to increase survival rates.
- 11.4 Vines protocol 2006-1565. The investigator requests permission to include harem breeding and allow pups to wean for 21-28 days depending on the size of the pup.
- 11.5 Wright protocol 2005-1487. The investigator requests to extend the weaning age of selected homozygous NT-3 lox runts to 28 days.
- **11.6** Yankee protocol 2005-1502. The investigator requests permission to extend the weaning age of mice no more than 28 days. Pups will generally be weaned between 24 26 days.
- 11.7 Yankee protocol 2005-1502. The investigator requests permission to include harem breeding and to not separate litters immediately after birth. Upon birth of the first litter, all mice will remain in the same cage. When the second litter is born, the first litter and mother will be removed within 72 hours of the birth of the second litter.
- 11.8 Psychological well-being of primates
 - **11.8.1** Buch projects no group housing due to inoculation of animals
 - **11.8.2** Stephens projects no group housing due to inoculation of animals.
 - 11.8.3 Cheney projects no group housing due to "caps" on heads of animals.
 - 11.8.4 Nudo projects no toys in cages because it interferes with manipulation studies.



FOIA 10-54911.8.5 An exemption for new monkeys, those that are young and not trained for transfer cages. Leave kong toys out of the cages until they are conditioned to the transfer cage. Toys prohibit a tight squeeze to force them into the cage. Other enrichments, including perches, food variety, mirrors, etc. will be maintained. Exemption is limited to not more than 2 months.

12.0 **Personnel training**

List will be attached to the minutes of the meeting. 12.1

13.0 **Repair tracking**

Description of Item Needing Correction	Location	Date Item Found	Estimated Completion Date	Committee Assigned Completion Date
Status				
Status				

14.0 **Programmatic issues**

- The last group of PI rooms is being moved from the LAR to KLSIC. The plan is to move as 14.1 many rooms as possible in anticipation of construction of the new cagewash. Space and research needs will be reassessed after construction. In addition, the LAR is doing extensive testing with sentinels. Any colonies testing positive will not be allowed to move.
- The purchase order for the new cagewash was submitted in March. Demolition of the existing 14.2 cage wash will begin at the end of June. Delivery of the new one is scheduled for mid-October. Also, dr. (b)(6), (b)(submitted a grant to NIH to fund additional ventilated racks.
- No major problems were indentified during the program and facility review. Investigator lab 14.3 inspections are currently being completed.
- The IACUC still plans to write a letter to administration asking for additional backing for the 14.4 LAR and infrastructure supporting animal research at KUMC.
- SOP for addenda Discussion to be held during the Executive Team meeting. 14.5

15.0 Other business

The annual compliance training window ended in March. Those not complaint with training 15.1 requirements will have network access suspended until training requirements have been met.





USDA, APHIS, Animal Care



ANIMAL WELFARE COMPLAINT

Complaint No.	Date Entered	Receive	з Ву		
FY#W10-131 Referred To	27-May-10	D.W.	-		
SACS/Inspector		Reply D	Je		
	son Complaint File	d Against			
Name UNIVERSITY OF K CENTER		Custome	er/License/Registration No. 3-R-0003		
Address 3901 RAINBOW BL	LVD VILION - MS 2014				
City KANSAS CITY	State KS	Zip 66160	Phone No 913-588-1206		
Complainant					
			_		
How was complaint email	received?				
Details of Com	plaint: Inadequate	animal care			
Results:			· · · · · · · · · · · · · · · · · · ·		
	•				
Application packet p	provided? Yes 🗌 No [·····	<u>,,,,,,,</u>	
INSPECTOR			DATE		
REVIEWED BY	······		DATE		

Building B, Mailstop 3W11 Fort Collins, CO 80526-8117

Dr. Gibbens,

I am contacting you on a matter of the utmost importance, the health and well-being of animals at the University of Kansas Medical Center 48-R-0003.

I am aware of several recent inspections that your staff performed regarding this facility. Clearly this laboratory has major problems as illustrated by the citations relevant to primates 2A0; 99R1027, 0A0, and 3A0 describe incidents of severe negligence by University of Kansas staff which resulted in extreme suffering for the animals involved in experimentation at UK.

However, I believe that these other situations at this facility which are also indicative of severe negligence. Two primates 1924 and 1941 (records attached) died of dehydration on Monday, 3/31/08. This took place after the facility had had problems with water pressure over the weekend. Both of these primates were found moribund (at the point of death). While the lab did initiate therapy, these primates should not have reached this point of severe dehydration. In fact, primate 1924 went into seizures later that day, even after receiving fluid therapy. As you know, seizures are associated with severe cases of dehydration. Clearly, these animals had not had access to water for a significant period of time to reach a point of such severe dehydration. This is a horrible way to die, and this facility deserves severe punishment.

Additionally, primate 1925 died on 3/29/08. This monkey was found on 2/29 to be moribund, hypothermic, non-responsive. This monkey also had a seizure, which can be associated with severe dehydration. And this monkey was found dead two days before 1924 and 1941. I have to wonder if 1925 succumbed to the same fate as 1924 and 1941. The death of this animal should be investigated because it may also be related to dehydration. I believe that these deaths represent violations of the animal welfare act regarding failure to provide adequate water to primates as well as instances of inadequate observation and care.

Primate 3A5 is listed as having "increased agitation and stress from morphine withdrawal" on 8/4/2009. The afternoon observation of the same date states "Patient is agitated and vocalizing more. Apears to be more aggressive and keeps moving from perch to floor and back. ... Patient is screeching very loudly when moving and grimacing a lot. Muscle tremors noted along with laying down in cage. ... PM (8:00) – Severe muscle tremors noted to the point that animal could not control his right leg and started to bite it – no lacerations or punctures noted."

On 8/5/2009 primate 3A5 is describes as "... similar to last night, severe muscle tremors when moving, a little ataxia with grimacing and screeching... Noon – Patient is doing better, significant tremors still noted, but screeching has decreased, appetite and fluid consumption is good. Face is a little flushed as well as mildly swollen on the right side. Afternoon/evening – Patient is very aggressive. ... Only about 20% of the Gatorade is gone from the am. Face is still flushed with possible hives." On 8/6/2009 "PM observation – Patient is having increased muscle tremors of legs and arms, will try and bite at feet if a large tremor occurs. No puncture wounds or lacerations noted on feet or legs." On 8/21/2009 3A5 is listed as "patient with vomit in cage yesterday afternoon and this am." On 8/25/2009 the record states "Vomit all over cage and floor in front of cage. Food left in cage....Right testicle is enlarged and left testicle is very small. Monkey is reserved today and will get up on perch only when approached." ON 8/26/2009 the record states "his testicles are swollen, enlarged and scrotum has purplish hue. His eyes are sunken, area around eyes are puffy and his pupils are dialated. He appears to be in pain from swollen scrotum. He will only move off of floor of cage with allot of stimulation. ... PI is consulting ... about options." On 8/27/2009 the record states "Monkey is very subdued and curled up on perch – will only move when stimulated a lot. Eyes are shrunken and dialated. Hair coat is spiked. Testicles are swollen, hard, and scrotum has purplish hue. Monkey did eat his biscuits, but it appeared that he vomited overnight." 3A5 was apparently killed that day because a necropsy was performed. The records do not contain information on when the euthanasia was performed, what drug was used, what dosage was given, etc. Also, this animal suffered for days, and should have been euthanized sooner, not dissimilarly to animal 3A0 previously mentioned above.

Primate84Z is listed in records as being on treatment with antibiotics from 7/29/09 – the morning of 8/4/2009 at which time the antibiotics were discontinued due to potential complications when the primate is put into morphine withdrawal, apparently as part of the protocol. Why was the protocol not delayed until this animal had completed antibiotic therapy? Why is an animal that is clearly suffering from a bacterial infection then thrown into morphine withdrawal?

On 8/4/2009 primate 84Z is described as "Patient is screeching a lot, grimacing noted as well. Patient is laying down in the bottom of the cage and will only move when stimulated. Muscle tremors noted. Appetite is decreased – no biscuits eaten, but has eaten fruit. ... Evening obs (8PM) – Patient is down in the bottom of the cage laying on his side. Will move when stimulated, but very reluctant. Screeching is excessive and grimacing noted when ever moving, mild muscle tremors noted. Appetite is still decreased, has eaten some of the fruit provided, but no biscuits. He has not touched the Gatorade."

On 8/5/2009 his record states "Am observations – patient is very reluctant to move on stimulation. Once he got up, he screeched once and then fell back over. Moderate muscle tremors noted. Appetite is severely decreased, a couple of biscuits eaten and some fruit. ... PM observation-Patient is sitting up on the floor, but reluctant to move, even when squeeze was used. No screeching noted, but muscle tremors are present and significant.

On 8/6/2009 his record states: Am Observation – Patient is sitting up this am, but still reluctant to move. Face is very red, but screeching was not noted this am. Appetite is still decreased with only a small amount of fruit eaten, no biscuits. Noon – Patient is down in cage and not responding to stimulation. Notify PI and continue supportive care. Afternoon – PI gave one does of morphine to try and off set withdrawal signs, no progress. Patient is down and only minimally responsive. 10:00 PM – Patient is euthanized per PI protocol.

In contrast to the record of primate 3A5, 84Z did not receive any rimadyl for pain relief. I also believe that this animal should have been euthanized sooner. Regarding both monkey 84Z and 3A5 the facility failed to euthanize these animals in a timely fashion and allowed them to suffer unnecessarily. It is also clear that these animals suffered unrelieved pain, and if they were not reported this way on the annual report filed by the University of Kansas Medical Center 48-r-0003, then this facility has violated requirements for reporting animals used in potentially painful experiments without anesthesia (column E). In fact, it appears that this lab may have violated these reporting requirements because experiments have been underway at this facility for several years which involve subjecting monkeys to withdrawal from addiction to morphine. Clearly, some of these animals have experienced unrelieved pain, However, this laboratory has not reported any monkeys in this category during 2006, 2007, or 2008.

Also, several monkeys at this have experienced fatal gastric bloat. These conditions have only been noticed when the animals are near death. They have included monkey A62, 94B and 99R1463. The records which I have obtained also discuss primate 21802. This monkey is also found moribund his record states: "Patient down, but minimally responsive. Very cold to touch. Evidence of hemorrhagic diarrhea round rectum. Pupils dilated and sluggish. ... Temp started at approx 75.5 degrees F. ... approximately 2 hours post treatment, patient had an episode of severe hemorrhagic diarrhea and went into respiratory arrest. Attempts to resuscitate failed." Clearly this monkey had been allowed to decline to an unacceptable level. The record states "history of mild diarrhea off and on for several months. Patient was on Pedialyte during the diarrheal events but no other treatment offered per PI protocol." Clearly this animal did not receive adequate treatment. Severe hemorrhagic diarrhea should be treated with much more than Pedialyte.

It is clear that the incidents which have been documented in the attached records which were obtained from the University of Kansas Medical Center through the state public records act. These documents clearly illustrate inadequate animal care which has allowed several animals to dies of dehydration, inadequate veterinary care which allowed several animals to suffer unnecessarily due to unreasonably delayed euthanasia, and a high incidence of death by gastric bloat which can be due to improper feeding of primates.

Also, it is clear that several of these primates have experienced unrelieved pain and distress and that University of Kansas Medical Center should be listing all primates used in experimentation that experience drug withdrawal in column E. It is apparent that this has not been the case, and that the lab has filed fraudulent reports.

Therefore, I officially request the treatment of the primates mentioned in this Official Complaint and take the most serious action allowable by the Animal Welfare Act against the University of Kansas Medical Center.

Sincerely,		
(b)(6)		

Sec. 2.33 Attending veterinarian and adequate veterinary care.

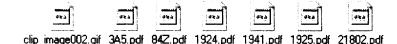
(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:

(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;
 (3) Daily observation of all animals to assess their health and

well-being;

Sec. 2.36 Annual report.

(7) State the common names and the numbers of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accempanying 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;



Primate Master Record

ID 345

DOB_____

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Date	Body Weight	Fecal Float	Fecal Culture	TB (eye)	СВС	B- Virus	Chemistry	Comments
1-5-4	4.70 mg							
2-3-09	4.85				~			
3-2-69	4.00				•			
3.70-8	4.66				V	-		
	4.80 kg				~			
6-2-08		~						(t) Guardie d Trick
19-29		+						
7-21-01	5.15 mg							
7,72,059		\checkmark						Negerne

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Primate Master Record

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DOB_____

					`* .			
Date	BW .	Fecal Float	Fecal culture	TB (eye)	CBC	B- Virus	Chemi - stry	Comments
12-12-07	3.8 35 Mg		~	12		~	2	-
, A.A.				R				
3.7.08	3.70m				5			
6-24- 5 8	4.15mg				\checkmark			
7-21-00	4.10149				\checkmark			
7-24-09					\checkmark			
8-04.0p					\checkmark			
F-11-08					~			
8-18-08					~			
9-16050	4.254				~			
G 14.08	4,46,49				-			
1-10-08	H.HOKA				~			
(2-08-08	4,4049		,		~			

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Treatment Record

Building/Room Number: Investigator: Species: RNSUS Animal ID: 3AS

Date	Treatment	Observations	Initials
64-58	BID Selling making: doordo		I m K Men
6-5-09	250mg Mehanidazote 1900 250mg Metaonidazot	8	AML PML
6-5-0A	.75ml LAP-DM		
6-6-69	250my Metroinidoal	Stool wermel	\$ April
6-7-69	25 Cmy metronideral	Gaff Stool	from Ppm
6/8/09	250 mg. Metroniated BED	Soft stool pm	NAME APP
6/9/09	350 mg Mehrninhzole BTD	soft stal	Have spin F
Glidog	250mg metron ichzole Birl		Kame Lin
	U		

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You have added a record to the LAR Medical Records Database with the following information. You may print this page to retain a copy of this record.

Record ID: 279073111 Record Added: 8/27/2009

Procedure Date: 8/27/2009 Primary Investigator: 4000 Protocol #: 2009-1811 Building/Room #: 4000 Species: Rhesus Macaque Unique Animal ID: 3A5 Number of Animals Operated: 0 Animal Group ID: Surgeon:

Not FOIA Deletions

Surgical Procedures:

Non-Surgical Procedures: Rimadyl was administered for pain management per interesting.

Survival Procedure: **True** Non-survival Procedure: **False**

Drugs/Doses Used: 0.50ml Rimadyl SQ for pain management perditionary.

Post Procedure Care:

Adverse Events:

Suture Removal Date:

General Medical Data:

Monkey is very subdued and curled up on perch-will only move when stimulated a lot. Eyes are sunken and dialated. Hair coat is spiked. Testicles are swollen, hard and scrotum has purplish hue. Monkey did eat his biscuits, but it appeared that he vomited overnight

Update this information

Add another record



You have added a record to the LAR Medical Records Database with the following information. You may print this page to retain a copy of this record.

Record ID: **1966690926** Record Added: **8/27/2009**

Procedure Date: 8/26/2009
Primary Investigator
Protocol #: 2009-1811
Building/Room #:
Species: Rhesus Macaque
Unique Animal ID: 3A5
Number of Animals Operated: 0
Animal Group ID:
Surgeon:
₩.

Not FOIA Deletions

Surgical Procedures:

Non-Surgical Procedures: Rimadyl administered for pain management per

Survival Procedure: **True** Non-survival Procedure: **False**

Drugs/Doses Used: 0.50ml Rimadyl SQ per distribution for pain management.

Post Procedure Care:

Adverse Events:

Suture Removal Date:

General Medical Data:

Monkey is more subdued than on 8-25-09. His testicles are swollen, enlarged and scrotum has purplish hue. His eyes are sunken, area around eyes are puffy and his pupils are dialated. He appears to be in pain from swollen scrotum. He will only move off of floor of cage with a lot of stimulation. He ate fruit given to him and soft food. PI is consulting with Definition about options.

Update this information

Add another record

You have added a record to the LAR Medical Records Database with the following information. You may print this page to retain a copy of this record.

Record ID: -1035991743 Record Added: 8/27/2009

Procedure Date: 8/25/2009 Primary Investigator: Protocol #: 2009-1811 Building/Room #: Species: Rhesus Macaque Unique Animal ID: 3A5 Number of Animals Operated: 0 Animal Group ID: Surgeon:

Not FOIA Deletions

Surgical Procedures:

Non-Surgical Procedures:

Survival Procedure: False Non-survival Procedure: False

Drugs/Doses Used:

Post Procedure Care:

Adverse Events:

Suture Removal Date:

General Medical Data: Monkey checked in the pm, no vomiting. Ate most of food but still subdued.

Update this information

Add another record

You have added a record to the LAR Medical Records Database with the following information. You may print this page to retain a copy of this record.

Record ID: **1251385920** Record Added: **8/27/2009**

Procedure Date: 8/25/2009 Primary Investigator: Protocol #: 2009-1811 Building/Room #: Species: Rhesus Macaque Unique Animal ID: 3A5 Number of Animals Operated: 0 Animal Group ID: Surgeon:

Not FOIA Deletions

Surgical Procedures:

Non-Surgical Procedures:

Survival Procedure: False Non-survival Procedure: False

Drugs/Doses Used:

Post Procedure Care:

Adverse Events:

Suture Removal Date:

General Medical Data:

Vomit all over cage and floor in front of cage. Food left in cage. Feces was mostly normal consistency, but a few pebbles. Right testicle is enlarged and left testicle is very small. Monkey is reserved today and will get up on perch only when approached. Gatorade removed to see if this stops vomiting-he will be monitored very closely.

Update this information

Add another record

You have added a record to the LAR Medical Records Database with the following information.

You may print this page to retain a copy of this record.

Record ID: -246369833 Record Added: 8/17/2009

Procedure Date: 8/7/2009 Primary Investigator: Protocol #: 2009-1811 Building/Room #1999 Species: Rhesus Macaque Unique Animal ID: 3A5 Number of Animals Operated: 0 Animal Group ID: Surgeon:

Not FOIA Deletions

Surgical Procedures:

Non-Surgical Procedures:

Am observation-Patient is up on perch and vocalizing. Face is flushed this am. He will hide his face and rub legs and arms occasionally. Feces is normal, all food is gone in cage from yesterday and most of the gatorade is drank. PM observation-Tremors are decreaed, appetite is very good. Did not drink orange gatorade. No other changes noted.

Survival Procedure: False Non-survival Procedure: False

Drugs/Doses Used:

Post Procedure Care: Continue gatorade supplementation and extra fruit with biscuits. Patient is improving daily.

Adverse Events:

Suture Removal Date:

General Medical Data: Continued observation for morphine withdrawal. Patient has been improving.

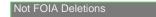
Update this information

Add another record

You have added a record to the LAR Medical Records Database with the following information. You may <u>print this page</u> to retain a copy of this record.

Record ID: -467008274 Record Added: 8/17/2009

Procedure Date: 8/6/2009 Primary Investigator: 1001/0009 Protocol #: 2009-1811 Building/Room #10000 Species: Rhesus Macaque Unique Animal ID: 3A5 Number of Animals Operated: 0 Animal Group ID: Surgeon:



Surgical Procedures:

Non-Surgical Procedures:

AM observation-Patient is doing much better this am. Muscle tremors are decreaed but still present. Appetite is increasing, most biscuits and fruit are gone from yesterday. Patient drank approx 1/3 of his gatorade from yesterday. Face is a little flushed, but that is also decreased. Noon obseravtion-Tremors seem a little worse, but no other changes noted. Appetite remains good-eating buscuits, canned food and fruit from this am. PM obseravation-Patient is having increased muscle tremors of legs and arms, will try and bite at feet if a large tremor occurs. No puncture wounds or lacerations noted on feet or legs. Patient has drank approx 20% of his gatorade from this am and appetite is unchanged.

Survival Procedure: False Non-survival Procedure: False

Drugs/Doses Used:

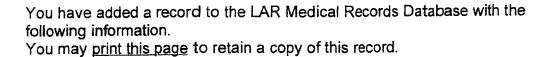
Post Procedure Care:

Recommend continue supportive care-gatorade, fresh fruit, biscuits and canned food as needed. Patient is doing better.

Adverse Events:

Suture Removal Date:

General Medical Data:



Record ID: 1697418503 Record Added: 8/6/2009

Procedure Date: 8/5/2009 Primary Investigator: **AutoChanne** Protocol #: 2009-1811 Building/Room #: **Species: Rhesus Macaque** Unique Animal ID: 3A5 Number of Animals Operated: 0 Animal Group ID: Surgeon:



Surgical Procedures:

Non-Surgical Procedures:

Am-Patient appears similar to last night, severe muscle tremors when moving, a little ataxia with grimacing and screeching. Gatorade consumption is approx 80% of the bottle from yesterday. Noon-Patient is doing better, significant tremors still noted, but screeching has decreased, appetite and fluid consumption is good. Face is a little flushed as will as mildly swollen on the righ side. Afternoon/evening-Patient is very aggressive. Approx 1/2 biscuits are gone as well as most of the canned food, fruit is mostly gone. Only about 20% of the gatorade is gone from the am. Face is still fluished with possible hives.

Survival Procedure: Faise Non-survival Procedure: Faise

Drugs/Doses Used:

Post Procedure Care:

Recommend continue gatorade and supplement with canned food and soft biscuits. Continue obseravtions, though overall, he appears to be doing better.

Adverse Events:

Suture Removal Date:

General Medical Data:

You have added a record to the LAR Medical Records Database with the following information. You may print this page to retain a copy of this record.

Record ID: -1850606882 Record Added: 8/6/2009

Procedure Date: 8/4/2009 Primary Investigator: **Constitution** Protocol #: 2009-1815 Building/Room **#Constitution** Species: Rhesus Macaque Unique Animal ID: 3A5 Number of Animals Operated: 0 Animal Group ID: Surgeon:

Not FOIA Deletions

Surgical Procedures:

Non-Surgical Procedures:

AM observations-Patient is aggitated and vocalizing more. Appears to be more aggressive and keeps moving from perch to floor and back. Appetite appears to be normal. Afternoon-Patient is screeching very loudly when moving and grimacing a lot. Muscle tremors noted along with laying down in cage. Patient is exhibiting increased aggression. Appetite is good stillmost biscuits are gone. PM (8:00)-Severe muscle tremors noted to the point that animal could not control his right leg and started to bite it-no lacerations or punctures noted. Appetite is good, most of the biscuits and fruit are gone as well as about 1/5 of the gatorade.

Survival Procedure: False Non-survival Procedure: False

Drugs/Doses Used:

Post Procedure Care: **Recommend add gatorade to cage in the afternoon to all withdrawal animals. Continue observation.**

Adverse Events:

Suture Removal Date:

General Medical Data: Health observations for morphine withdrawal.

Primate Master Record

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DOB 27-08

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Date	Body Weight	Fecal Float	Fecal Culture	TB (eye)	СВС	B- Virus	Chemistry	Comments
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2-3-09	4.25 124				~			
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Primate Master Record

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be done.	Signed:				Clinic Employee	(viewab	le)
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You have added a record to the LAR Medical Records Database with the following information.

You may print this page to retain a copy of this record.

Record ID: 644208997 Record Added: 8/11/2009

Procedure Date: 8/6/2009 Primary Investigator: 499 Protocol #: 2009-1815 Building/Room #: 499 Species: Rhesus Macaque Unique Animal ID: 84Z Number of Animals Operated: 0 Animal Group ID: Surgeon:

Not FOIA Deletions

Surgical Procedures:

Non-Surgical Procedures:

Am Observation-Patient is sitting up this am, but still reluctant to move. Face is still very red, but screeching was not noted this am. Appetite is still decreased with only a small amount of fruit eaten, no biscuits. Patient drank approx 40% of gatorade. Noon-Patient is down in the cage and not responding to stimulation. Notify Pl and continue supportive care. Afternoon-Pl gave one dose of morphine to try and off set withdrawal signs, no progress. Patient is down and only minimally responsive. Able to pull patient out by hand and supplement with fluids and warm blankets. 6:30pm-Patient is unchanged-recommend euthanasia. 10:00pm-Patient euthanized per Pl protocol.

Survival Procedure: False Non-survival Procedure: True

Drugs/Doses Used:

Morphine-PI records-approx 3pm. SQ fluids-120mls at approx 2pm-patient had drank well the night before-no fluids in the am. Warm blankets-wrap patient in warm blankets, repeat every 1-2 hours as needed.

Post Procedure Care:

Adverse Events:

Euthanasia recommend since patient is not responding to fluids and warming and appears to be getting worse. Compared to the other withdrawal monkeys, this individual is no recovering. Approx 10pm, all

staff and supplies organized and patient euthanized-see PI protocol.

Suture Removal Date:

Not a FOIA Deletion

General Medical Data: Continued obserations and treatments for Morphine withdrawal.

Update this information

Add another record



You have added a record to the LAR Medical Records Database with the following information. You may print this page to retain a copy of this record.

Record ID: **732875339** Record Added: **8/6/2009**

Procedure Date: 8/5/2009 Primary Investigator: Protocol #: 2009-1815 Building/Room #: Species: Rhesus Macaque Unique Animal ID: 84Z Number of Animals Operated: 0 Animal Group ID: Surgeon:

Not FOIA Deletions

Surgical Procedures:

Non-Surgical Procedures:

AM observations-patient is very reluctant to move on stimulation. Once he got up, he screeched once and then fell back over. Moderate muscle tremors noted. Appetite is severely decreased, a couple biscuits eaten and some fruit. Gatorade is only approx 20% gone from yesterday. Noon-osbervation-Patient is up and sitting on perch, hunched posture, red face, but responsive. Patient ate most all fruit, a small amount of canned diet. Seems to be improving. PM observation-Patient is sitting up on floor, but reluctant to move, even when squeeze back was used. Gatorade is appox 20% gone. No screeching noted, but muscle tremors are present and significant. Appetite still is decreased, but soft biscuits are spread throughout cage bottome indicating some usage.

Survival Procedure: False Non-survival Procedure: False

Drugs/Doses Used:

Post Procedure Care:

SQ fluids, PM-was able to lightly squeeze patient and provide 100mls of SQ saline over hip area-a small amount of hemorrhage noted on completion. Once finished the patient moved to the back of cage and layed down. Recommend continued obseration and assessment for fluid supplementation based on gatorade consumption.

Adverse Events:

Suture Removal Date:

Not a FOIA Deletion

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General Medical Data: Continued health obseravtions after Morhine Withdrawal.

Update this information

Add another record



You have added a record to the LAR Medical Records Database with the following information. You may <u>print this page</u> to retain a copy of this record.

Record ID: -882365724 Record Added: 8/4/2009

Procedure Date: 8/4/2009 Primary Investigator: Protocol #: 2009-1815 Building/Room #: Species: Rhesus Macaque Unique Animal ID: 84Z Number of Animals Operated: 0 Animal Group ID: Surgeon:

Not FOIA Deletions

Surgical Procedures:

Non-Surgical Procedures:

Am obs-Patient is active, but increased vocalization. Stool is formed but soft. Face and ears are errythematous. Appetite appears normal. Afternoon obs-Patient is screeching a lot, grimacing noted as well. Patient is laying down in the bottom of the cage and will only move when stimulated. Muscle tremors noted. Appetite is decreased-no biscuits eaten, but has eaten fruit. Gatorade added to cage. Evening obs (8pm)-Patient is down in teh bottom of the cage laying on his side. Will move when stimulated, but very reluctant. Screeching is excessive and grimacing noted when ever moving, mild muscle tremors noted. Appetite is still decreased, has eaten some of the fruit provided, but no biscuits. Has not touched the gatorade.

Survival Procedure: False Non-survival Procedure: False

Drugs/Doses Used:

Post Procedure Care:

Continue with gatorade and extra fruit. Continue observation, due to protocol restrictions, no other treatment as this time.

Adverse Events:

Suture Removal Date:

General Medical Data:

Not a FOIA Deletion

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Health observations-morphine withdrawal started at noon on 8/3/09.

Update this information

Add another record

You have added a record to the LAR Medical Records Database with the following information. You may print this page to retain a copy of this record.

Not FOIA Deletions

Record ID: -2017030321 Record Added: 8/4/2009

Procedure Date: 8/4/2009 Primary Investigator: Protocol #: 2009-1815 Building/Room #: Protocol #: 2009-1815 Building/Room #: Protocol #: 2009-1815 Species: Rhesus Macaque Unique Animal ID: 84Z Number of Animals Operated: 0 Animal Group ID: Surgeon:

Surgical Procedures:

Non-Surgical Procedures:

Due to the increased stress of the morphine withdrawal, recommend d/c antibiotics. Potential for adverse affects from the antibiotics could worsen the clinical signs of withdrawal (GI upset, vomiting. Recommend recheck fecal and start antibiotics again if needed post withdrawal.

Survival Procedure: False Non-survival Procedure: False

Drugs/Doses Used:

Post Procedure Care: Recommend continued observation.

Adverse Events:

Suture Removal Date:

Not a FOIA Deletion

General Medical Data: D/C metronidazol and LAP due to morphine withdrawal per PI protocol.

Update this information

Add another record

ID__

231 of 241

Microchip ID#	450850565D
Primate Mast	er Record
Pat	DOB 1/31/0

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Date	BW .	Fecal Float	Fecal culture	TB (eye)	CBC	B- Virus	Chemi - stry	Comments
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9/4/02		Franciskin		5				
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1	O.Cro			R				TB-SERVEL 417A exp - H-30-04
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LAR Medical Records Database FOIA 10-549

You have added a record to the LAR Medical Records Database with the following information. You may print this page to retain a copy of this record.

Record ID: 689158828 Record Added: 5/13/2008

Procedure Date: 3/31/2008 Primary Investigator: Protocol #: 2004-1470 Building/Room #: Species: Squirrel Monkey Unique Animal ID: 1924 Number of Animals Operated: 0 Animal Group ID: Surgeon:

Not FOIA Deletions

Surgical Procedures:

Non-Surgical Procedures:

Patient moribund on exam. Hypothermia, tachypnea, tachycardia, 8-10% dehydration via skin tent noted. Blood glucose at 80. Initiated fluid therapy, and supportive care. 1:00pm-patient is actually worse with fluid therapy. Repeat blod glucose at 45. D/C fluid therapy. Continue rest of supportive care. 1:30pm-patient seizured for approx. 1 minute. Elected euthanasia at this point.

Survival Procedure: False Non-survival Procedure: True

Drugs/Doses Used: LRS-20ml IP. 2ml Beuthanasia IV.

Post Procedure Care:

Adverse Events: Necropsy-no urine in bladder, kidneys pale. Moderate amount of IP fluid left over. No other abnormalities.

Suture Removal Date:

General Medical Data:

Animal staff found 1924 and 1941 down in their cages this am. They are both on the same cage. The lixits were working, but the staff found that the water pressure to the floor was low. Weekend staff reported no

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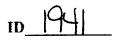
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problems with water or lixits over the weekend.

Update this information

Add another record





DOB

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Date	BW 7	Fecal Float	Fecal culture	TB (eye)	CBC	B- Virus	Chemi - stry	Comments
2/2-11	6801		13			۰.	7 J.	· · · ·
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3/14/2)_\$9Sh	<i>,</i>		10			\checkmark	
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11-19-03	0.445 mg			KR.				TB-2002 4124 Exp-7-14-64
5-28-06	0.875- Hg			KR			~	
3-71-00	P	uts end	en	then'	red.	·		
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You have added a record to the LAR Medical Records Database with the following information. You may print this page to retain a copy of this record.

Record ID: **1489421111** Record Added: **5/13/2008**

Procedure Date: 3/31/2008 Primary Investigator: Protocol #: 2004-1470 Building/Room #: Species: Squirrel Monkey Unique Animal ID: 1941 Number of Animals Operated: 0 Animal Group ID: Surgeon:

Not F	Deletions	

Surgical Procedures:

Non-Surgical Procedures:

PE: Patient is 8-10% dehydrated and moribund on exam. Patient was responsive to stimulus, but would lay still when not being examined. Tachycardia and tachypnea noted. Hypothermia along with tachy mucous membranes. Blood glucose is at 101. IV access was not attained, 25ml LRS given IP over 3 hours. Patient kept warm with heated water bottles and warm towels. 1:00pm-patient's skin tent is better, approx. 3-5% dehydrated. No urine production. Oral supplementation of pedilyte started. 3:00pm-Patient has become comatose-non-responsive. Patient euthanized with 2ml Beuthanasia D IV.

Survival Procedure: False Non-survival Procedure: True

Drugs/Doses Used: LRS IP-approx 25 mls. 2ml Beuthanasia D.

Post Procedure Care:

Adverse Events:

Necropsy-kidneys were pale, no urine in bladder. Part of the IP fluids had not been absorbed even after 6 hours. Suspect acute renal failure due to dehydration.

Suture Removal Date:

General Medical Data:

Animal husbandry staff found 1941 and 1924 down in cage this am. Both were on the same rack. The water lixits were working, but staff found that the water pressure to the floor was low. Weekend staff did not note any problems with the water.

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Not a FOIA Deletion

Update this information

Add another record

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ID_O	Ж				*** **		DC	DB 2/19/0/ Formale
Date	BW .	Fecal Float	Fecal culture	TB (eye)	СВС	B- Virus	Chemi - stry	Comments
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1-31-63	0.630			KR				TB acoral 487.4 821-7-14-04
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You have added a record to the LAR Medical Records Database with the following information.

You may print this page to retain a copy of this record.

Record ID: -1936877618 Record Added: 5/13/2008

Procedure Date: 3/29/2008 Primary Investigator: Protocol #: 2004-1470 Building/Room #: Species: Squirrel Monkey Unique Animal ID: 1925 Number of Animals Operated: 0 Animal Group ID: Surgeon:

Not FOIA Deletions

Surgical Procedures:

Non-Surgical Procedures:

PE: Patient moridund on exam, BG at 25. Hypothermic, reflexes are decreased or non-responsive. Pupils are dilated, but sluggish. Tachycardia and tachypnea noted. Oral and IV dextrose started along with IP fluids. Patient wrapped in warm towels and warm water bottles. 10am-patient still moribund, repeat BG showed 80. 10:30am-patient had a seizure that lasted approximately 30 seconds. With no response to blood glucose in normal range, patient euthanized with 2ml Beuthanasia IV.

Survival Procedure: False Non-survival Procedure: True

Drugs/Doses Used: 1% Dextrose IV, LRS IP, 2ml Beuthanasia D IV

Post Procedure Care:

Adverse Events:

Suture Removal Date:

General Medical Data: Weekend staff found patient down in cage this am.

Update this information

Add another record

Primate Master Record

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Date	BW -	Fecal Float	Fecal culture	TB (eye)	CBC	B- Virus	Chemi - stry	Comments
7-1-04	5.0504			R			1	
7-13-64				12				
3-28-07	5.165kg				•			

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You have added a record to the LAR Medical Records Database with the following information. You may print this page to retain a copy of this record.

Record ID: -1048511840 Record Added: 1/17/2008

Procedure Date: 10/15/2007 Primary Investigator: Protocol #: 2004-1430 Building/Room #: Protocol #: 2004-1430 Building/Room #: Protocol #: 2004-1430 Species: Rhesus Macaque Unique Animal ID: 21802 Number of Animals Operated: 0 Animal Group ID: Surgeon:

Not FOIA Deletions

Surgical Procedures:

Non-Surgical Procedures:

Exam-Patient down, but minimally responsive. Very cold to the touch. Evidence of hemorrhagic diarrhea around rectum. Pupils were dilated and sluggish. Heart had normal sounds, but erratic rhythm. Lungs mild les noted dorsally (dependent edema possibly). IV catheter set in and warm saline given. Temp started at approx. 75.5 degrees F. See attached readout from monitoring equipment. Bld glucose was normal at 88. Continued warming of patient and fluids, but approximately 2 hours post treatment, patient had an episode of severe hemorrhagic diarrhea and went into respiratory arrest. Attempts to resuscitate failed (atropine, oxygen, epinephrine, CPR).

Survival Procedure: False Non-survival Procedure: False

Drugs/Doses Used:

Post Procedure Care:

Adverse Events:

Suture Removal Date:

General Medical Data:

Patient found down in cage in the afternoon check. History of mild diarrhea off and on for several months. Patient was on Pedilyte during the diarrheal

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events, but no other treatment offered per PI protocol.

Update this information

Add another record