



USDA-APHIS-Animal Care



ANIMAL WELFARE COMPLAINT		
Complaint No. AC22-729	Date Entered: May 27, 2022	Processed By: Andrew Butz
Referred To: AUTUMN UNCK		Reply Due: June 26, 2022
Facility or Person Complaint Filed Against		
Name: BIOANALYTICAL SYSTEMS INC	Customer No.: 784	License No.:
Address: 10424 MIDDLE MT. VERNON ROAD		Email Address:
City: MOUNT VERNON	State: IN	Phone No.:
Complainant Information		
Name: (b) (6), (b) (7)(C), (b) (7)(D)	Organization: (b) (6), (b) (7)(C), (b) (7)(D)	
Address:		Email Address: (b) (6), (b) (7)(C), (b) (7)(D)
City:	State:	Phone No.:
How was the Complaint received? Email		
Details of Complaint: See Attached		
Results: An unannounced focused inspection was conducted on May 26, 27 and 31, 2022 and an inspection report was completed. An extensive review was conducted of facility records, to include daily activity logs, animal health records, and various other documentation.		
Application Kit Provided: Yes: No:		
Inspector: REBECCA NANNEY		Date: June 3, 2022
Reviewed By: AUTUMN UNCK		Date: June 6, 2022



Inspection Report

BIOANALYTICAL SYSTEMS INC
10424 MIDDLE MT. VERNON RD
MOUNT VERNON, IN 47620

Customer ID: **784**
Certificate: **32-R-0020**
Site: 001
BIOANALYTICAL SYSTEMS, INC

Type: FOCUSED INSPECTION
Date: 26-MAY-2022

2.31(c)(3)

Institutional Animal Care and Use Committee (IACUC).

During the IACUC semi-annual inspection conducted in Oct. 2021, there were deficiencies noted that were identified as being significant. The correction date of the significant finding was to be completed by the end of Nov. 2021 but was not confirmed as being corrected until Dec. 9, 2021. The facility did not report this lapse in correction until early Jan. 2022, which was more than 15 business days past the original correction date.

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 to APHIS and any Federal agency funding that activity.

Corrective actions taken include highlighting any significant findings in a bold red font and adding a more thorough method to track progress of completion, such as calendar reminders.

Correct by adhering to correction dates set for deficiencies noted during semi-annual inspections.

Corrected actions in place prior to inspection date.

Prepared By: REBECCA NANNEY
USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL
OFFICER

Date:
02-JUN-2022

Received by Title: Attending Veterinarian

Date:
02-JUN-2022



Inspection Report

2.38(f)(1) Critical

Miscellaneous.

*On Nov. 30, 2021, a male Cynomolgus macaque (~1.5-2 kg), a stock animal, was found dead in a slide style restraint chair while out for a routine cage change/sanitization. It was the second time these primates had been placed in restraint chairs. Also, during this restraint period, there was a female that had to be removed from the chair due to not acclimating well to the restraint and was placed into a slide and clip style chair with no further issues. Prior to this date, it was noted that a male had to be removed due to not acclimating well to the restraint and was placed into a slide and clip style chair with no further issues. He was persistently trying to escape from the chair and appeared to be compromising his respirations in the attempt. There were two (2) technicians present during the routine cage change/sanitization, one primarily observing the primates in the chairs and the other cleaning/sanitizing the animal room.

*On March 10, 2022, a male Cynomolgus macaque (~1.5 kg), a stock animal, was found unresponsive in a restraint chair during an animal room sanitization. He was removed from the chair and the veterinary staff was immediately notified. Upon veterinary exam, no respiratory effort or pulse was noted, and he was pronounced dead. It was the second time he had been placed in a restraint chair which was equipped with a slide style top. Shortly after this incident on the same day, a second primate began to show signs of distress in a slide style restraint chair, and he was immediately removed from the chair and given oxygen before recovering. There were at least three (3) technicians in very close proximity. Mitigation efforts were planned to modify the chairs in this building to restrain the collar only but were delayed due to a shortage of hardware. Approximately 50% of the chairs had already been modified and the remaining were modified by the end of the day.

The previous style of the primate restraint chairs (slide style), in combination with the primate collars and size of the

Prepared By: REBECCA NANNEY
USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER

Date:
02-JUN-2022

Received by Title: Attending Veterinarian

Date:
02-JUN-2022



Inspection Report

primates available, did not adequately protect the animals from injury during handling.

*On Dec. 7, 2021, a male pig (5M024, repeat dose toxicity study) was evaluated due to lameness that had persisted since Dec. 6, following a toxicokinetic blood collection, during which manual restraint was used. Upon palpation of the right distal hind limb, the Attending Veterinarian noted swelling and crepitus, as well as a likely fracture of the mid-tibia. Deep palpation, further diagnostics and treatment were not performed due to the scheduled necropsy of this animal on that day. Euthanasia and necropsy occurred after the examination (on Dec. 7). Necropsy revealed fractures in both the tibia and fibula.

Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort.

Corrective actions already taken for the primates: the restraint chairs have been modified, additional monitoring has been instigated and there is a plan to review and implement an acclimation process.

Correct by further evaluating handling techniques and devices, conduct appropriate training or re-training as needed, and evaluate methods of monitoring, to include the importance of proper care and monitoring of all animals.

3.125(a)

Facilities, general.

A female pig (#3088782, 4F053) was witnessed on Aug 19, 2021, as being loose from her primary enclosure with a male pig (4M023). This was recorded as a potential mis-mating between the animals, as this facility does not breed animals. On Sept. 16, 2021, the female was administered inhalation anesthesia by mask for Lutalyse injections to terminate any

Prepared By: REBECCA NANNEY
USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL
OFFICER

Date:
02-JUN-2022

Received by Title: Attending Veterinarian

Date:
02-JUN-2022



Inspection Report

potential pregnancy.

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

Correct by evaluating all enclosures (primary and secondary) and repairing as needed to protect and contain the animals.

Correction date: June 17, 2022

This inspection was conducted with Attending Veterinarian, Team Leader of Veterinary Care, IACUC chair and other facility representatives.

This exit interview was conducted with Attending Veterinarian, Team Leader of Veterinary Care, IACUC chair, Chief Operations Officer and other facility representatives.

Additional Inspectors:

Michael Schnell, VETERINARY MEDICAL OFFICER

Prepared By: REBECCA NANNEY
USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER

Date:
02-JUN-2022

Received by Title: Attending Veterinarian

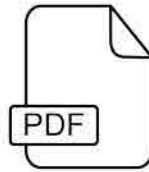
Date:
02-JUN-2022



Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
784	32-R-0020	001	BIOANALYTICAL SYSTEMS, INC	26-MAY-2022

Count	Scientific Name	Common Name
000000	NONE	NONE
000000	Total	



CFR:3.125(a)

Photographer: Rebecca Nanney

Certificate: 32-R-0020

Date and Time: 5/31/2022 3:00 PM

Legal Name: BIOANALYTICAL SYSTEMS INC

Inspection No: 2016090000794504

Facility Name: BIOANALYTICAL SYSTEMS, INC

Description: 3.125(a): Copy of facility's treatment log for the Lutalyse injection on a female pig after the animal escaped her primary enclosure and was loose with a male pig.

COPY

Signature

Inotiv Controlled Form
Document: FRM.DSA.001
Effective: 01 August 2020

Revision: 000

inotiv
analyze. answer. advance.

Title: Inotiv Evansville Animal Evaluation and Treatment Sheet

Page 1 of 1

Study/Stock Animal #(s): 4F053

USDA #: 3088782

Species: Swine

Study Number: [REDACTED]

Room #: A1316

Date: 16 Sep 21

Evaluation

Activity/Behavior: <u>Normal</u>	Temperature (°F): <u> </u>
Respiration Rate (breaths/min): <u> </u>	Pulse (beats/min): <u> </u>
Mucous Membranes: <u> </u>	Capillary Refill Time (seconds): <u> </u>

Due to potential mismating witnessed on 19 Aug 21 when pig was found out of run with a male pig (4M023), two intravulvar injections (5mg each) about 6-8 hours apart were administered today to terminate any potential pregnancy; lidocaine cream 4% was applied at each injection (lot 20FP1485 exp 6/22)

Medication: <u>Lutalyse Injection</u>	Manufacturer: <u>Zoetis</u>	Expiration Date: <u>Oct 2023</u>
Amount of Medication: <u>5mg</u>	Frequency: <u>twice 6-8 hrs. apart</u>	Lot #: <u>476033</u>
		Route of Administration: <u>intravulvar</u>

Enter Day #	Tx Day: <u>1</u>	Tx Day:	Tx Day:	Tx Day:	Tx Day:
Enter Date	<u>16 Sep 21</u>				
Medication Given: Initial	Tx1 Tx2 Tx3	Tx1 Tx2 Tx3	Tx1 Tx2 Tx3	Tx1 Tx2 Tx3	Tx1 Tx2 Tx3
	<u>[REDACTED]</u>				

Enter Day #	Tx Day:	Tx Day:	Tx Day:	Tx Day:	Tx Day:
Enter Date					
Medication Given: Initial	Tx1 Tx2 Tx3	Tx1 Tx2 Tx3	Tx1 Tx2 Tx3	Tx1 Tx2 Tx3	Tx1 Tx2 Tx3

Enter Day #	Tx Day:	Tx Day:	Tx Day:	Tx Day:	Tx Day:
Enter Date					
Medication Given: Initial	Tx1 Tx2 Tx3	Tx1 Tx2 Tx3	Tx1 Tx2 Tx3	Tx1 Tx2 Tx3	Tx1 Tx2 Tx3

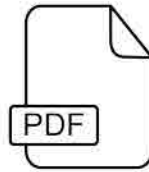
Additional Comments: (1) Given at 10:30 AM. 16 Sep 21 (2) Given at 12:30 PM. 16 Sep 21

Animal maintained at ~5% isoflurane via mask inhalation for injections
lot G25B17A exp 31 JAN 22 16 Sep 21

Study Director: [REDACTED]

Attending Veterinarian: [REDACTED]

(2) (C) 16 Sep 21



CFR:2.38(f)(1)

Photographer: Rebecca Nanney

Certificate: 32-R-0020

Date and Time: 5/31/2022 3:00 PM

Legal Name: BIOANALYTICAL SYSTEMS INC

Inspection No: 2016090000794504

Facility Name: BIOANALYTICAL SYSTEMS, INC

Description: 2.38(f)(1): Copy of facility's electronic journal entry and necropsy report regarding the pig with a broken leg after handling for a blood collection.

Session Comment	5M024 was evaluated this morning due to a lameness that had persisted since yesterday following a TK collection. Upon palpation of the right distal hind limb, swelling and crepitus was noted as well as a likely fracture of the mid-tibia. Since this pig was scheduled for necropsy soon after evaluation, deep palpation, further diagnostics, and treatment were not performed. Lesion will be examined at necropsy.	07- Dec- 2021	14:14:19	Yes	07- Dec-2021 14:21:59 CST
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Animal Sheet Report

Page : 2 / 3

Study : [REDACTED]

Test Item : [REDACTED] Sponsor : [REDACTED]
Test System : Pig, REPEAT DOSE TOXICITY Created : 26-May-2022 14:14:30 CDT

ANIMAL NUMBER : 5M024 SEX: Male DOSE GROUP: 5

Defined Sacrifice Group : K0

State at Necropsy : Terminal sacrifice

Date of Necropsy : 07-Dec-2021

Days on Test : 274 (09-Mar-2021 - 07-Dec-2021)

* MACROSCOPIC OBSERVATIONS

BONE, TIBIA

-01: Fracture, middle

GALLBLADDER

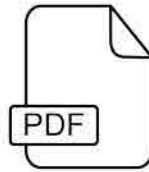
-01: Abnormal consistency, firm, Contents: dark material

BONE, FIBULA

-01: Fracture, middle

NO OTHER MACROSCOPIC OBSERVATIONS NOTED

CONFIDENTIAL



CFR:2.38(f)(1)

Photographer: Rebecca Nanney

Certificate: 32-R-0020

Date and Time: 5/31/2022 3:00 PM

Legal Name: BIOANALYTICAL SYSTEMS INC

Inspection No: 2016090000794504

Facility Name: BIOANALYTICAL SYSTEMS, INC

Description: 2.38(f)(1): Copy of letters from facility to AAALAC regarding the two primates that died during handling.

December 7, 2021

INOTIV - EVANSVILLE
10424 MIDDLE MOUNT VERNON RD.
MT. VERNON, IN. 47620



AAALAC International
5205 Chairmans Ct #300
Frederick, MD 21703

RE: Unit Number 000877

To whom it may concern:

In accordance with AAALAC's FAQ, I.2, an incident of unexpected animal death is reported.

Incident: On 30 November 2021, I was made aware of a male cynomolgus monkey (~1.5-2.0 kg) that was found dead in a restraint chair while out for a routine cage change/sanitization. This monkey was part of a shipment of 34 animals that arrived in early November 2021. I entered the holding area, confirmed death, and examined the monkey. He appeared to be in good body condition and well-hydrated but had some loose stool with a moderate amount of frank blood. Rectal swabs were collected for PCR. A postmortem examination was performed, and major organs were collected in 10% NBF for microscopic evaluation by a veterinary pathologist. The pathology report is pending.

It is important to note that this was only the second time this room of monkeys had been placed in restraint chairs. I interviewed two technicians that were present during the routine cage change. One technician was observing the monkeys in the chairs, and the other technician was cleaning/sanitizing the animal room. The first technician interviewed was present and observed the first cage change for these monkeys and reported that one male monkey had to be removed from the chair because he was not acclimating well. He was persistently trying to escape from the chair and appeared to be compromising his respirations in the attempt. He was placed in a slide and clip style chair with no further incident. During the second cage change approximately 2 weeks later, a female was found in a similar situation and was removed and placed in a slide and clip style chair with no further incident. Not long after, a male was noted in a restraint chair with his mouth open and pale. Upon removal from the chair, the monkey was unresponsive, not breathing, and there was no pulse. I was notified and confirmed death when I arrived.

Corrective Action: Results of the investigation revealed that no SOPs were violated. One technician was observing the animals while out in chairs which is evident through the recognition and mitigation of two similar situations with animals struggling with acclimation. The cause of death is still pending the report from a staff veterinary pathologist. No interventions will be taken at this time until a final pathology report is received and reviewed by pertinent staff.

The results of the report can either be sent in a separate communication or shared with AAALAC representatives that will be on site in February 2022. Please let me know what you would prefer. If you have any further questions/concerns or need clarification, please contact me at [REDACTED]

Sincerely,

[REDACTED]

7 Dec 21

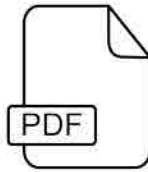
Attending Veterinarian

cc:

[REDACTED]

analysis: 0.000000 0.000000





CFR:2.31(c)(3)

Photographer: Rebecca Nanney

Certificate: 32-R-0020

Date and Time: 5/31/2022 3:00 PM

Legal Name: BIOANALYTICAL SYSTEMS INC

Inspection No: 2016090000794504

Facility Name: BIOANALYTICAL SYSTEMS, INC

Description: 2.31(c)(3): Copy of letter from facility to APHIS to notify of the missed correction date from the semi-annual inspection and failure to notify APHIS within 15 business days.

January 06, 2022

BASI — EVANSVILLE
10424 MIDDLE MOUNT VERNON RD.
MT. VERNON, IN. 47620

USDA APHIS Animal Care
2150 Centre Ave.
Building B, Mailstop 3W11
Fort Collins, CO 80526



To whom it may concern:

I am writing to inform you of an issue that was not addressed or reported in a timely manner. In October of this year, significant findings were observed during a routine facility inspection by our IACUC. Mild mold growth was noted around vents in six rooms, four of which were vacant of animals. The significant findings were to be resolved by the end of November 2021 but were not completed until December 8-9. We must assume the significant finding was not resolved by the deadline as the two rooms that were occupied with animals were sanitized on November 23 and 24, but removal of mold growth was not documented until December 8-9.

The IACUC failed to recognize the lapse in completion until early January 2022. After discussing the concern with Dr. Rebecca Nanney with USDA-APHIS, she recommended notifying you of the situation.

If you have any questions or need clarification, you may call or email me directly.

Sincerely,


Senior Vice President, Preclinical Services
Bioanalytical Systems, Inc.




Animal and Plant
Health Inspection
Service

Animal Care

Fort Collins Office
2150 Centre Avenue
Building B, 3W11
Fort Collins, CO 80526
Phone: 970-494-7478

May 27, 2022

(b) (6), (b) (7)(C), (b) (7)(D)

Dear Complainant,

Thank you for your correspondence dated May 25, 2022. We are reviewing your concerns and assigned tracking number AC22-729. Please allow us enough time (30 to 60 days) to thoroughly look into your concerns. You may submit a request to the Animal and Plant Health Inspection Service (APHIS) Freedom of Information Act (FOIA) office to obtain any publicly available information regarding our review.

FOIA Requests can be submitted three ways:

1. Web Request Form: <https://efoia-pal.usda.gov/App/Home.aspx>
2. Fax: 301-734-5941
3. US Mail:
USDA- APHIS- FOIA
4700 River Road, Unit 50
Riverdale, MD 20737

Should you have any questions regarding the APHIS FOIA process or need assistance using the Web Request Form **please contact the APHIS FOIA office at 301-851-4102.**

Animal Care is a program within the U.S. Department of Agriculture (USDA) that directs activities to ensure compliance with and enforcement of the Animal Welfare Act and the Horse Protection Act. Animal Care establishes standards of humane treatment for regulated animals and monitors and achieves compliance through inspections, enforcement, education, and cooperative efforts under the Acts.

Please be assured that we will look into your concern(s) and take appropriate action(s).

Thank you for your interest into the humane treatment of these animals.

Sincerely,

Elizabeth Goldentyer, D.V.M.
Deputy Administrator
USDA, APHIS, Animal Care

From: [Unck, Autumn M - MRP-APHIS](#)
To: [Butz, Andrew L - MRP-APHIS](#)
Subject: FW: [External Email]Inotiv Complaint for USDA APHIS Consideration
Date: Wednesday, May 25, 2022 12:59:33 PM
Attachments: [image003.jpg](#)
[image004.jpg](#)
[image005.jpg](#)
[image006.png](#)
[Inotiv- USDA Complaint Final.pdf](#)

Hi Andy,

Can you enter this in eFile so the inspectors can move forward with this complaint in the field?

Thanks!

BTW its to be assigned to Rebecca Nanney and the facility is Bioanalytical Systems Inc.

CID# 784

Certificate –32-R-0020

Respectfully,

Autumn

Autumn Unck, DVM

Supervisory Animal Care Specialist (Detail) – Michigan and Indiana

402-679-4283

From: Gibbens, Robert - MRP-APHIS <robert.m.gibbens@usda.gov>
Sent: Tuesday, April 19, 2022 5:09 PM
To: Rhyner, Aaron A - MRP-APHIS <aaron.a.rhyner@usda.gov>; Unck, Autumn M - MRP-APHIS <autumn.m.unk@usda.gov>
Subject: FW: [External Email]Inotiv Complaint for USDA APHIS Consideration

From: (b) (6), (b) (7)(C), (b) (7)(D)
Sent: Tuesday, April 19, 2022 4:05 PM
To: Goldentyer, Betty J - MRP-APHIS <betty.j.goldentyer@usda.gov>; Gibbens, Robert - MRP-APHIS <robert.m.gibbens@usda.gov>; Mullaney, Roxanne C - APHIS <roxanne.c.mullaney@usda.gov>
Cc: (b) (6), (b) (7)(C) <hs1f.org>; (b) (6), (b) (7)(C) < [\(b\) \(6\), \(b\) \(7\)\(C\)@humanesociety.org](mailto:(b) (6), (b) (7)(C)@humanesociety.org)>; (b) (6), (b) (7)(C) < [\(b\) \(6\), \(b\) \(7\)\(C\)@humanesociety.org](mailto:(b) (6), (b) (7)(C)@humanesociety.org)>
Subject: [External Email]Inotiv Complaint for USDA APHIS Consideration

[External Email]

If this message comes from an **unexpected sender** or references a **vague/unexpected topic**;

Use caution before clicking links or opening attachments.

Please send any concerns or suspicious messages to: Spam.Abuse@usda.gov

Betty, Bob and Roxanne,

Thank you again for meeting with us today to discuss the attached complaint. For reference,

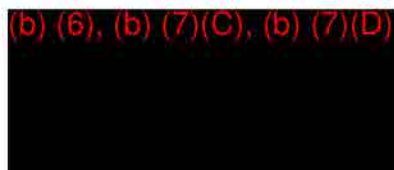
I've also attached the discussed log notes.

We will work on getting the video to the Riverdale office ASAP.

Please let us know if you have any questions, we're happy to answer anything that comes up!

Best,

(b) (6), (b) (7)(C), (b) (7)(D)

A large black rectangular redaction box covering the signature area.

To support our work, please make a [monthly donation](#) or [take action](#).





THE HUMANE SOCIETY
OF THE UNITED STATES



HUMANE SOCIETY
LEGISLATIVE FUND™

April 19, 2022

Kevin Shea, Administrator
USDA Animal and Plant Health Inspection Services
1400 Independence Ave., SW
Washington, DC 20250

Dear Mr. Shea,

We are writing to inform you of an investigation we have recently concluded at Inotiv (formerly Bioanalytical Systems), a USDA-registered research facility located in Mt. Vernon, IN. We would greatly appreciate the USDA investigating what we allege could be violations of the federal Animal Welfare Act and taking enforcement action as appropriate. The facility's USDA number is 32-R-0020.

The alleged AWA violations we believe occurred during our 163-day investigation include:

- Failure to provide appropriate and timely veterinary care – including euthanasia and including on weekends and holidays – to sick, injured and moribund primates, pigs and dogs;
- Failure to monitor animals in vulnerable circumstances; during the investigation at least two primates died by accidental hanging in their restraint chairs;
- Failure to minimize pain and distress in animals;
- Failure to have a sufficient number of employees to ensure humane care of animals;
- Failure to maintain the facility's structures to ensure proper function - including over-heated rooms where animals are held during summer months, mold growing in closets and light fixtures, collapsed ceilings, damaged/taped floors in hallways and sewage back-ups in animal labs;
- Failure to educate staff, most of whom had no idea what test substances they were administering nor what the MSDS information was for those substances;
- Failure to conduct simple animal husbandry tasks such as nail clipping.

We discovered other issues having to do with the quality of animal care at Inotiv, including the lab's failure to provide humane endpoints in animal toxicology studies and possibly failing to provide instructions to personnel as to what constitutes a humane endpoint, affecting rodents, dogs, and primates in studies. During our investigator's months in the lab, they never heard the phrase "humane endpoint" used but did see an AAALAC inspection report that identified the lack of humane endpoints as a concern for AAALAC.

We have attached exhibits that recount what we know about certain toxicology studies at Inotiv and how we believe they may have violated the AWA and its implementing regulations. However, there are areas and materials at Inotiv's Mt. Vernon facility to which our investigator had no access. The USDA's November 16-19, 2021, Inspection Report of Inotiv's Envigo facility in Virginia and the appalling violations documented there, including cruelly killing conscious puppies with intracardiac injections, cause us great concern about Inotiv's company policies and processes. Therefore, in addition to investigating the potential AWA violations detailed in the attached exhibits, we also request that the USDA carefully review the following at Inotiv:

Euthanasia – our investigator never had access to the necropsies or euthanasia of animals. We do not know if the killing methods used at Inotiv's Envigo facility are used at the Mt. Vernon, IN location. Near the conclusion of our investigation, six out of eight stock/practice dogs were "sacrificed for stock colony reduction." We would like to be assured that these dogs – who could have been adopted out instead of killed – and all animals in Inotiv's laboratories are properly euthanized.

IACUC – our investigator did not have access to IACUC meeting minutes but did know the names of its members. Given the findings of AAALAC as to the absence of humane endpoints, we ask that APHIS thoroughly review IACUC proceedings, and protocol proposal and review processes, at Inotiv. It is our belief that there may have been times when voting members were not adequately informed about the nature of test articles or previous studies using those same substances. While the



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C did seem to meet [REDACTED] of including [REDACTED], an Attending Veterinarian and a non-scientist, we
and appreciate [REDACTED] of the committee's composition and related expertise to ensure the committee is able to
requirements are met. One committee member is the head of maintenance at Inotiv who previously
at a paint store.

human primate transport – On February 24, 2022, approximately [REDACTED] molgus macaques were unloaded at Inotiv's
Mt. Vernon, IN lab from [REDACTED] in Lou [REDACTED] (b) (6), (b) (7)(C) [REDACTED] We cannot tell from
[REDACTED] where is [REDACTED] temperature [REDACTED] inside the trailer and our investigator did not
trailer, but it is conceivable that the primates [REDACTED] in temperatures of 4 [REDACTED] or less for more than 45
in violation of 9 [REDACTED] temperature on 2.24.22 did not rise about 34 degrees [REDACTED] do not know how
primates traveled in the box trailer. We ask A [REDACTED] investigate the use of [REDACTED] particular trailer and determine
whether it was appropriate [REDACTED] and travel [REDACTED]

y, with [REDACTED] investigator [REDACTED] as still working at Inotiv, a sponsor that had two [REDACTED] toxicology [REDACTED] there – one using
and [REDACTED] primates [REDACTED] a press release stating that it was abandoned [REDACTED] substance (ALG020572)
being used in those animal studies because [REDACTED] serious adverse effects to the point [REDACTED]
hospitalization. The [REDACTED] [REDACTED] that both studies on mice (1772-21807) and primates (1772-21189) were
stopped but that the animals [REDACTED] to be dosed and [REDACTED] and [REDACTED] to be drawn until a written
amendment to the protocol [REDACTED] investigator [REDACTED] action could take weeks. We [REDACTED] greatly
[REDACTED] [REDACTED] on this matter to ensure that [REDACTED] amendment has been [REDACTED] s
[REDACTED] been [REDACTED] [REDACTED] toxicity studies [REDACTED]

will provide whatever video or log notes that APHIS believe [REDACTED] on. We will also provide our
investigator [REDACTED] interview if you believe it is [REDACTED] sary.

while, we are grateful [REDACTED] in this matter.

Sincerely yours,

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

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

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

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

Dr. Betty Goldentyer, DVM, Director, Administrator, Animal Care
Robert Gibbons, DVM, Director, Animal Welfare Operations



6-211013 – violations of 9 C.F.R. (d), 2.33

[illegible]

per group. [redacted] veterinary care [redacted] the second dosing [redacted]
[redacted]ing from mouth, 4M00 [redacted] saliva, [redacted]ing from mouth and vo [redacted]g, 4F015 – pacing, foaming from
[redacted]n, vomiting.

On Sunday, November 7, 2021, the dogs were dose [REDACTED] observed [REDACTED] on the group 4 dogs were b [REDACTED] I
ema of the ears, bilate [REDACTED] lateral conjunctiva redness, [REDACTED] mucous membrane, inc [REDACTED],
[REDACTED] and ad [REDACTED] body tremor [REDACTED] ability to stand on their own. Dog 4M008 [REDACTED] which point the
[REDACTED] rker/tech again called the veterinarian. [REDACTED]

and 4F016 to necr

icology study on a [REDACTED] [REDACTED] has no vete [REDACTED] in present until
21, our i [REDACTED] [REDACTED] old that p [REDACTED] s were expected with the
[REDACTED] [REDACTED] started on Friday, September 5, 2021 [REDACTED] unavailable to
staff was nev [REDACTED] the nature of the substance they were
and 5:

...ce talking about rang... studies and MTD studi... he... are
ending in 211013 [MORPH... (b) (6), (b) (7)(C) because "they're
g to do that".

11.05.2021_11:04: [REDACTED] asking about dog study 3036-211013 Morphic MR-14113 oral gavage 2x daily range-finding [REDACTED] to obs...The dogs in A. And [REDACTED] I did it this morning they do [REDACTED] hea. And I did call some [REDACTED] trembling [REDACTED] the red mucus [REDACTED]

[REDACTED] failure to plan for a [REDACTED] adequate veterinary care are [REDACTED]g this study [REDACTED]ars [REDACTED]te AWA implementing provisions governing research facilities, which require advance veterinary consultation, the capacity to provide adequate primary care [REDACTED]d weekends), and the actual provision of adequate veterinary care. See 9 C.F.R. §§ 2.31(d)(1)(iv) procedures that [REDACTED]ore than [REDACTED]ight [REDACTED] will...involve, in t[REDACTED]anning, [REDACTED]ic [REDACTED]ne a [REDACTED]g veterinarian [REDACTED]r designee”, 2.31(d)(1)(v) (“Medical care for animals will be available and provided as necessary by qualified veterinarians”), 2.33(a) (“Each research facility shall have an attending



inarian who shall provide equivalent care of it...), 2.33(b) ("Each research facility shall establish and maintain program...veterinary care that include...(1)The availability of appropriate...personnel...to comply with this subchapter; (2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and the availability...and holiday care") (emphases added).

her concern to use that more studies using the same Morphic s...that caused so much suffering in the above-referenced study...ed at...do not know...ations of these studies.

, an AAALAC inspection that occurred while...investigation was under...the lab pointed out that Inotiv to consider human...ch is surely the case with the dogs in the Morp...kicology study.



bit II

7-21878 – violations of 9 C.F.R. § 1.61(d), 2.33

767-21878, sponsored by IFM Management, was a chronic toxicity study using an unknown substance.

There were 8 males and 8 females in the study which started on March 1, 2022 for the males and March 4 for the females.

Our investigator's cover sheet (b) (6), (b) (7)(C) told (b) (6), (b) (7)(C) study meeting. At the project's start, the study

(b) (6), (b) (7)(C) let (b) (6), (b) (7)(C) the state (b) (6), (b) (7)(C) if they're gonna live or die."

On March 4, 2022 (b) (6), (b) (7)(C) starts from the prior day's dosing. He experienced decreased activity, labored breathing, extremely rapid heart rate and a temperature of 105. He was noticeably unsteady while sitting in his cage. The facility (b) (6), (b) (7)(C) and the study (b) (6), (b) (7)(C) the dog would be closed again on March 4 despite these observations.

The March 4 study chronic toxicity study was started just one day (b) (6), (b) (7)(C) days (males) prior to the weekend.

On March 4, 2022, conversation (b) (6), (b) (7)(C) this study, between (b) (6), (b) (7)(C) and (b) (6), (b) (7)(C) investigator, indicate the possible absence of humane endpoints. Transcript (b) (6), (b) (7)(C) taped conversations are provided below. From (b) (6), (b) (7)(C) notes:

2_INO_C006: Study 17 (b) (6), (b) (7)(C).

(b) (6), (b) (7)(C) feel like you already have symptoms."

(b) (6), (b) (7)(C) On day (b) (6), (b) (7)(C) after the first fucking dose."

Me: "Yea so shouldn't you have a plan?"

(b) (6), (b) (7)(C) "That's what I'm saying (b) (6), (b) (7)(C) finding study you, the study director, the study manager (b) (6), (b) (7)(C) to

(b) (6), (b) (7)(C) and (b) (6), (b) (7)(C) if we see the (b) (6), (b) (7)(C) plan of action."

(b) (6), (b) (7)(C) then discusses how she was going to take a temp and then dose each dog this weekend, but now will take all

(b) (6), (b) (7)(C) temperatures first in (b) (6), (b) (7)(C) the vet and send (b) (6), (b) (7)(C) multiple dogs will have high

(b) (6), (b) (7)(C) You know he's at a level where (b) (6), (b) (7)(C) can have (b) (6), (b) (7)(C) minute.

(b) (6), (b) (7)(C) and watch it, let the

(b) (6), (b) (7)(C) heavily depending on (b) (6), (b) (7)(C)

(b) (6), (b) (7)(C) Yes. He does (b) (6), (b) (7)(C)

(b) (6), (b) (7)(C) with this plan (b) (6), (b) (7)(C) I'm sorry, but (b) (6), (b) (7)(C) what, get an

(b) (6), (b) (7)(C) for 4M007 was 105.1 per (b) (6), (b) (7)(C) researches

(b) (6), (b) (7)(C) n, so I'd say he got it."

(b) (6), (b) (7)(C) infection?"

(b) (6), (b) (7)(C) Me: "That was (b) (6), (b) (7)(C) the (b) (6), (b) (7)(C) said to watch for?"

(b) (6), (b) (7)(C) was, they ran it for 3 days (b) (6), (b) (7)(C) hina. And they handled a

(b) (6), (b) (7)(C) read the protocol. It was (b) (6), (b) (7)(C) 3 consecutive days on 7 dogs or

(b) (6), (b) (7)(C) trust that."

(b) (6), (b) (7)(C) in re (b) (6), (b) (7)(C) o..."

(b) (6), (b) (7)(C) I'm really scared I'm (b) (6), (b) (7)(C) come into a dead (b) (6), (b) (7)(C) I'd (b) (6), (b) (7)(C) beat (b) (6), (b) (7)(C) y's (b) (6), (b) (7)(C) gonna be pissed."

(b) (6), (b) (7)(C) 2022_INO (b) (6), (b) (7)(C) 9: (b) (6), (b) (7)(C) administers test article to group 4 female dogs in study (b) (6), (b) (7)(C) 1878 (b) (6), (b) (7)(C) states that she is also

(b) (6), (b) (7)(C) ed about a (b) (6), (b) (7)(C) having (b) (6), (b) (7)(C) sh (b) (6), (b) (7)(C)

(b) (6), (b) (7)(C) e (b) (6), (b) (7)(C) because (b) (6), (b) (7)(C) know this is h (b) (6), (b) (7)(C)

(b) (6), (b) (7)(C) "That's my thing. Even if you (b) (6), (b) (7)(C) oh we don't (b) (6), (b) (7)(C) have a plan just in case."



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Because earlier when [REDACTED] said, [REDACTED] say. You [REDACTED] to make it through the weekend unless they're
[REDACTED]ing. What [REDACTED]

[REDACTED]ing? Because that dog is obviously [REDACTED] difficulty breathing, increased heart rate, it's got a temp of
[REDACTED] that's just going [REDACTED] (b) (6), (b) (7)(C)

022_INO_C0010 [REDACTED] administers test article to 4M007 in dog study 1767-21878. She says, "I'm so sorry" to the dog.

03.04.2022_INO_C001 [REDACTED]'s test [REDACTED] study 1767-21878

01 [REDACTED] 7 in dog study 1767-21878

NO_C0014: 4M007 in dog study 1767-21878

022_INO_C0015: (b) (6), (b) (7)(C) [REDACTED] is the white blood cell count is one for 4M007. [REDACTED] asks if they will
[REDACTED] him today (referencing euthanasia). Dog study 1767-21878.

[REDACTED] know with [REDACTED] let it run its course [REDACTED]

We'll probably have to go [REDACTED] in a moribund condition first."

When [REDACTED] his temp [REDACTED] again, and it is 105.4.

Unfortunately, our investigator was not scheduled [REDACTED] it was told when they returned to work [REDACTED]

that dog 4M007 had [REDACTED] on Saturday, March 5, and dog 4M008 had been euthanized on Sunday,

6. The investigator was [REDACTED] that euthanasia was [REDACTED] because the lab had a
difficult [REDACTED] reaching the [REDACTED] ornia.

March 8, 2022 (b) (6), (b) (7)(C) [REDACTED] told our investigator what she had learned [REDACTED]

[REDACTED] over the previous week [REDACTED] from the investigator's log/video notes:

[REDACTED] break [REDACTED] and I then went to Building H [REDACTED] worked on dog [REDACTED] administered test article to
the remaining 14 dogs in this study (2 group 4 male [REDACTED] were [REDACTED]), while I restrained. All [REDACTED]
appeared to be in good [REDACTED]

[REDACTED] also able to discover that the previous study for dog study 1767-21878 was held in China. The study was 3 male dogs
consecutive day [REDACTED]

[REDACTED] group 4 males are gone in study 1767-21878 [REDACTED] that on [REDACTED]
[REDACTED] better now. I ask (b) (6), (b) (7)(C) [REDACTED] even know what the drug is for?"

[REDACTED] So it's fucking [REDACTED] and spongy [REDACTED] discolored. And [REDACTED] lesions on
[REDACTED] golf ball size [REDACTED] is heart...It's messing with the Thymus

[REDACTED] but this study and its [REDACTED] in the dogs took place [REDACTED] (b) (6), (b) (7)(C) and the
[REDACTED]'s log/video notes:

[REDACTED] work on dog [REDACTED] 1767-21878 [IFM 14-day range-finding] [REDACTED] did the [REDACTED] blood
draw for the [REDACTED] lining [REDACTED] tells me the 2 group 4 females were euthanized the week before, because of showing

[REDACTED] 03.16.2022_INO_C009 [REDACTED] drew blood from the 6 male
[REDACTED] to be in good condition. [REDACTED] did tell me [REDACTED] pup 3 male lost

[REDACTED] starting to exhibit [REDACTED] because of test article (see
[REDACTED] 2022 [REDACTED] 16 dogs, 8 males and 8 females; the study now has 12 dogs, 6 males and 6

[REDACTED] es. The males go to [REDACTED] tomorrow.

2022_INO [REDACTED] 9: [REDACTED] and I talking about dog study 1767-21878.

Those two [REDACTED] talk, and [REDACTED] [REDACTED]
[REDACTED] the [REDACTED] females this [REDACTED] last week, later last week (referring to the 2 group 4 females). They
[REDACTED] like crashing. So do you remember how that, the [REDACTED] losing weight (referring to the group 4 male dogs)?



Yea.”

(b) (6), (b) (7)(C) “The group (referring to 8% of body weight), in like, between Sunday and today. I’m kinda glad he’s tomorrow because I think it’s start hit them now.”

eat. Makes me w or anything about the study because...”

(b) (6), (b) (7)(C) “...because t 7 consecutive days, no signs v me levels as group 3, and I’m like
shmmm, I don’t know I feel about that.”

h f dmin ary care g this study appears to violate AWA implementing governing research facilities, which require ad veterinary consultati adequate guidance to personnel ng euthanasia dec mals experiencing severe suffering, the capaci provide adequate ary care (including on weekends), and the act vision of adequate veterinary care. See 9 C.F.R. §§ 2.31(d)(1)(iv) cedures that or slight pain d will...involve, r planning, ation with the attending narian or his or her designee”, 2.31(d)(1)(v) (“Animals that would otherwise rene ere or ch in or distress that cannot be relieved will be pain anized.. piate, during the ure (d)(1 care for animals will be available and p s a qualified veterinarian”), 2.33(a) (“Each research facilit an who shall provide adequate vete animals”), 2.33(b) (“...lity shall establish and maintain programs of adequate veterinary care that e...(1)The availability of nel...to comply w isid s subchapter; (2) The use of appro methods to pr , and tre njuries, and the availability of gency, nd , e”: (4) Guidance to...personne n th and use phases)

k that APHIS review the veterinary records for dogs used euthanasia was promptly used ate ng and whether the IACUC w rmed of the p y in China. This may be an example of when the IACUC should have been made studie s Samantha claimed, the dose nt increased remarkably f the Chinese study, there sh have been justification ng e of oup 4 dogs. (b) (6), (b) (7)(C) claim that the attending veterinarian di f the drug is also ncerting.



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did food consumption. The dog [redacted] fed them [redacted] did not eat her soft food from yesterday and did not [redacted] the new soft food [redacted] her.

clinical observation [redacted] 21636. Many of the dogs were underweight, and many of the dogs in [redacted] 2 & 3 were [redacted] labeled in Ascentos (our computerized [redacted] on system) as loss of weight/skinny.

When leaving for the [redacted] saw [redacted] (b) (6), (b) (7)(C) told her [redacted] in Building H with [redacted] and [redacted] 636 [redacted] he told [redacted] that the dog 2F026 had not eaten her food. I told [redacted] so did not eat the food from the day before. [redacted] told us that no one [redacted] this study to last the entire time [redacted] there are already [redacted]

October 6, 2021 [redacted] was taken to [redacted] investigator's Octo [redacted] 2021, [redacted] notes:

with [redacted] and w [redacted] study ending in 3064-21636 [Crinetics C [redacted] gavage]. We gave [redacted] hydrocortisone to groups 4 & 5. We then dos [redacted] administering oral gavage and me restrai [redacted] the two vet techs. (b) (6), (b) (7)(C) came to the study and evaluated 3F030. The dog was energetic but did not [redacted] eight and was emaciated [redacted] dog into a vehicle [redacted] psy. [redacted] said they may take another [redacted] fema [redacted] the study for [redacted] did not [redacted]

5.2021 [redacted] are going to " [redacted] dog for this study [redacted] to we have to get a body weight and bleed it [redacted] doses group 4 and 5 dogs [redacted] Cortisone.

2021 [redacted] 003: 3F030 for body weight. [redacted] comments tha [redacted] ing, and I say she's just not [redacted] eating. The dog weighed 5.4 kg [11.9 LBS]. The vet, (b) (6), (b) (7)(C) asks [redacted] if the dog has eaten anything. [redacted] says [redacted] a little, but not a lot. [redacted]'s going to look at female 26 [redacted] ause she isn't eating eit [redacted] in [redacted] to do blood draw for [redacted] dy ending in 21636)

2021_INO_C0 [redacted] the room with [redacted] 030. [redacted] s, "You're not supposed [redacted] a blood draw for [redacted] ending in 21636 [redacted] said she had [redacted] blood pressure ([redacted])

[redacted] is about possi [redacted] ing to take this dog (to necropsy) as

references he has a c [redacted] e call today for studv [redacted] in [redacted] (b) (6), (b) (7)(C) offers 3F030 soft food [redacted] eat it, don't let [redacted] eat it (because [redacted], but was [redacted] then says don't document that [redacted] red food. [redacted] mentions dog [redacted] er 9 [redacted] ill investigate further) is not eating as well. (study ending in 21636)

[redacted] are on soft food for n [redacted] ating/poor b [redacted] lition. (study

2021_INO_C0014: 3 [redacted] dog air carrier to b [redacted] orte [redacted] necropsy [redacted] o [redacted] carrier, with dog, into [redacted] vehicle to transport to ne [redacted] (study ending in 21636)

2021_INO_C [redacted] oing o [redacted] rm [redacted] is company/test [redacted] (study [redacted] 2 [redacted] rine [redacted]



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2021_INO_C0018 [REDACTED] es of [REDACTED] le I restr [REDACTED] says, "I was really hoping they would've taken all these off study... [REDACTED] IUCAC is having a meeting about the study. (study ending in 21636)

2021_INO_C0019 [REDACTED] s study and says if this study has the lethal effects like it did in the study, he would [REDACTED] they would only use groups 4 [REDACTED] (ps). I say that it seems to be only groups 2 & [REDACTED] are having trouble [REDACTED] says that they are the ones that were supp [REDACTED] have trouble.

04 [REDACTED] asked [REDACTED] ropsy f [REDACTED] 0 in study ending in 21636.

Really pale for or [REDACTED] oid were extremely pale, the pituitary looked l [REDACTED] was about to e.

study is this? (a man from [REDACTED] known dept)

63 [REDACTED] ly the [REDACTED] thyroid. All (unintelligible) really pale, an [REDACTED] right. We didn't call them for anything, but they just said pretty m [REDACTED] everything. So I think they're gonna g [REDACTED] ty (biology). Kinda what [REDACTED] about when you take a dog down early. Hoping that you can explain what [REDACTED] ned, especially with the [REDACTED] y. So they're supp [REDACTED] TH [REDACTED] made in the pituitary, so the pituitary [REDACTED] probably think [REDACTED] ing, so ke [REDACTED] ing, making it. It gets it all jack [REDACTED] and ramped [REDACTED] m [REDACTED] little discs, they have a unique [REDACTED] hem [REDACTED] it was like [REDACTED] brown [REDACTED] up like it was [REDACTED] explode.

Do you have any idea how those bloods came back from [REDACTED] [REDACTED] looked pretty decent, surprisingly. I got a meeting a few minutes.

Between them to kill [REDACTED] ng study ending in 21636)

ask if they take [REDACTED] le tomorrow [REDACTED] fere [REDACTED] study.

le [REDACTED], the goals. I mean, they're, I t [REDACTED] ve're rea [REDACTED] sidering. but I don't know. G [REDACTED] probably it'll be [REDACTED] like a normal [REDACTED] isone gr [REDACTED] d be kinda [REDACTED] of that group if they didn't [REDACTED] supposed to [REDACTED] ogs that are ge [REDACTED] re doing just a neat. Everyt [REDACTED] makes sense. Just makes you wonder [REDACTED] t would be great for people with Cushings, how do you ever

do a proper study between [REDACTED] an [REDACTED] r n [REDACTED] [REDACTED] re's all th [REDACTED] ndary effects of cortisol. Trying [REDACTED] round th [REDACTED] now that's there. [REDACTED] here [REDACTED] rect toxicity. It's hard to hash that out whenever it's what they're trying to do with the [REDACTED] ng about 21636)

worker that anot [REDACTED] og (3M009) from 21636 was sent to necropsy.

October 15, 2021 our i [REDACTED] or observed that "n [REDACTED] dog [REDACTED] groups 2 a [REDACTED] tin [REDACTED] pear emaciated and [REDACTED] eing fed soft food, as v [REDACTED] ave their weight loss/emaciation documented in Ascentos."

study continu [REDACTED] 0.2021 [REDACTED] d [REDACTED] which point all wer [REDACTED] to



's failure to plan for [redacted] veterinary [redacted] this study appears to violate AWA implementing regulations governing [redacted] facilities, which require advance veterinary consultation, adequate guidance to personnel regarding euthanasia decisions, timely euthanasia of [redacted] experiencing severe suffering, and the provision of adequate veterinary care. See 9 C.F.R. [redacted] procedures that may cause more than momentary or slight pain or distress to animals will... [redacted] in their planning, consultation [redacted] veterinarian or his or her designee"), (1)(v) ("Animals [redacted] would otherwise experience severe or chronic [redacted] or distress that cannot be relieved will be painlessly euthanized. [redacted] during [redacted] (vii) ("Maximum [redacted] will be available and [redacted] by [redacted] lified [redacted] ("Each [redacted] facility shall have an attending veterinarian who [redacted] adequate veterinary care of its animals"), 2. [redacted] "Each research facility [redacted] establish and maintain programs [redacted] adequate veterinary care [redacted] ability of appropriate...personnel...to comply with [redacted] provisions of [redacted] chapter; (2) The use of appropriate methods [redacted] prevent, control, diagnose [redacted] and treat diseases and injuries, and the [redacted] ability of emergency [redacted].. (4) Guidance [redacted] in the care and [redacted] of animals [redacted] ng...euthanasia").

[redacted] should [redacted] precisely [redacted] its assessment of whether this study was [redacted] other study to which staff referred during this study.



bit IV

5-21894 - violations of 9 C.F.R. § 2.33

dy was 14-day LP oral gavage exploratory to [redacted] dogs who were dosed twice daily at eight-intervals for Cedilla therapeutics.

th [redacted] by the [redacted] on November 14, 2021, when the investigator restrained the [redacted] blood draws and dosing. On this day, the investigator and their coworker [redacted] were required to watch an [redacted] seminar about how [redacted] dogs, while working on the study. This kind of distraction during an [redacted] study seems inadvisable but it was required due to Inotiv's Envigo breeding facility in Virginia being exposed - recently the result [redacted] All employees [redacted] knowing they had [redacted] the [redacted] r.

em [redacted] 2021 [redacted] investigator worked on this study again, res [redacted] [redacted] ge. It is on this day the investigator began to see problems with excessive [redacted] days, the investigator was told that [redacted] s [redacted] 6 dogs in this study [redacted] growths in their throats.

From [redacted] December 17, 2021

wo [redacted] study 2815-21894. I restrain [redacted] while [redacted] administe [redacted] e [redacted] p 3 female [redacted] [redacted] test article [redacted] tells me to continue [redacted] [redacted] moved to ensure she received test article and [redacted] her with not vomiting. The [redacted] dog does vomit a little and foams at [redacted] outh. This dog has a different gavage tube, smaller in diameter [redacted] [redacted] inserting gavage tube, she can [redacted] spoon [redacted] growth in the throat area, [redacted] inhibits the tube [redacted] [redacted] also told me one group 4 male (4M007) had been euthanized and sent to necropsy [redacted] showed [redacted] biological side effects and was unable to [redacted] (will investigate further [redacted])

ops of dogs (and all other animals at Inotiv) are identified by color on tags and gavage tube. The colors are as follows:

e- Group 1

Group 3 female

rent. Even after I pull [redacted] out for a little bit, kind [redacted] b i [redacted]. At [redacted] like she's got a, it's like you [redacted] ally [redacted] st [redacted] g difficulty inserting [redacted] big deal. It's to be expected [redacted]

gavage toxicity study - G [redacted] otherwise - if she had a [redacted] was to be expected, it [redacted] d to unders [redacted] y the study

December 18, 2021, 3F [redacted] test article and [redacted] me [redacted] after ga [redacted] th [redacted] investigator was told [redacted] other dog - 4F015 - also [redacted] ns to have a blockage. A significant conversation takes place about dog 4M007 who died [redacted] s euthanized [redacted] the study. During the conversation, the investigator's coworker [redacted] reve [redacted] at the study director [redacted] ot know what [redacted] s [redacted] m [redacted] this [redacted] r apparently told [redacted] that this [redacted] e [redacted] dy d [redacted] - that there [redacted] port of "contamination [redacted] ing the first study.



the December 18, [REDACTED] /vid [REDACTED]: [REDACTED]

[REDACTED] study 2815-21894. I restrained while [REDACTED] administered test article via oral gavage. The 2nd group 3
3F014, vomited [REDACTED] after gavage. Another dog in study ending in 21894, 4F015, also
to have a "b[REDACTED]" according to Brett, video C [REDACTED]

I then restrained while [REDACTED] [REDACTED] the [REDACTED] study end [REDACTED] up 3 female dog again
The [REDACTED] study [REDACTED] in okay [REDACTED] condition.

021_INO_C003: N [REDACTED] 007 in study 2815-21894.
[REDACTED] "Yea, I heard one of your group 4 males went do [REDACTED] quickly."

[REDACTED] "Yea, it was weird. The [REDACTED] one, the other group 4 male, was fairly similar in the beginning, but he ended up popping
up."

Me: "That's good."

[REDACTED] "It's weird."

[REDACTED] "Yea, [REDACTED] might I bet that study director [REDACTED] is lying to him when
[REDACTED] [REDACTED] that first day [REDACTED]."

[REDACTED] "That's what I told him. It's so weird, the complete oppo [REDACTED] Cause you know we were here
while [REDACTED]."

[REDACTED] "Yea, yea we were here [REDACTED] that, the last dose was like at [REDACTED] or 4."

[REDACTED] "The females the following day, they did have a lit [REDACTED] it. The males may have the first day, and I just didn't notice it
were so subtle [REDACTED] ching tremor [REDACTED] it was [REDACTED], very minor...I think I ca [REDACTED]
[REDACTED] probably would have no [REDACTED]

[REDACTED] "If you to look for it [REDACTED]

[REDACTED] "He didn't kno [REDACTED] it do. So, this [REDACTED]...there was a [REDACTED] with this drug one
[REDACTED] the kind of con [REDACTED] tion, or something. So, pretty much a

[REDACTED] "don't recognize it."

[REDACTED] "In the, UNINTELLIGIBLE [REDACTED] done anything [REDACTED] them for a while.
[REDACTED] to be done [REDACTED] it. Louis site. But, I don't know if [REDACTED] the ones th [REDACTED] ed
something up [REDACTED] past [REDACTED] st didn't have the means of doing this study."

[REDACTED] dog.

[REDACTED] "You always act like [REDACTED] gonna throw it up but [REDACTED] ever [REDACTED] st taste [REDACTED] ta [REDACTED] buddy?"

[REDACTED] then tells [REDACTED] h [REDACTED] is head up for just a second.

[REDACTED] [REDACTED] [REDACTED] to group 4 fen [REDACTED] 015.



(b) (6), (b) (7)(C) "She's got a slight [redacted] in her [redacted]."

[redacted] think it is?"

(b) (6), (b) (7)(C) don't know. (b) (6), (b) (7)(C) thought it was like an aortic [redacted] formed wrong."
(b) (6), (b) (7)(C) then administers [redacted] gavage to second group 4 female dog.

(b) (6), (b) (7)(C) 09: [redacted] adminis [redacted] al gavage [redacted] I restrain. Group 3 female vomits test article

[redacted] encourage APHIS to [redacted] out this study, Inotiv violated AWA implement [redacted] regulations
[redacted] research facilities, which require advance [redacted] consultation, the [redacted] vision of adequate veterinary care
[redacted] ding appropriate [redacted] (injuries), proper [redacted] conducting procedures, and
[redacted] nce of unnecessary duplication of previous experiments. See 9 C.F.R. §§ 2.31(d)(1)(iii) (approval requires "assurance
[redacted] the articles do not necessarily duplicate previous experiments"), 2.31(d) [redacted] Procedure [redacted] may cause more
[redacted] pment [redacted] or slight [redacted] stress to the animals will...involve, in their [redacted] [redacted] with the attending
veterinarian or his or her designee"), 2.31(d) [redacted] procedures...will be appropriately qual [redacted]
[redacted] in those procedure [redacted] ("Medical care for animals will be available and provided as necessary by a
[redacted] ed veterinarian"), 2.33(a) [redacted] facility shall have a [redacted] vet [redacted] who shall provide adequate
veter [redacted] re of its animal [redacted] research fac [redacted] sh and maintain programs of a [redacted] ate
[redacted] ary [redacted] de... (2) The use of appropriate [redacted] to [redacted] t, contro [redacted]
[redacted] lies... ([redacted] g [redacted] post-procedure [redacted] in accordance [redacted]
[redacted] ng procedures.")

[redacted] could app [redacted] APHIS making a determin [redacted] as to whether (b) (6), (b) (7)(C) [redacted] examined the dogs or had run
appropriate diagnostic tests to determine the reason [redacted] tions [redacted] is "aortic arch" theory was just [redacted] less
[redacted] what was wrong with [redacted]

[redacted] believe the study director should have known the name of the test article and should have imparted this information to
[redacted] working on the [redacted]

[redacted] les [redacted] of whether this study was duplication of the [redacted] using th [redacted]



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bit V

1718-21546 - violations of 9 C.F.R. 31(d), 2.33

1718-21546 was performed by MacroGenics and was a pharmacokinetic and tolerability study on eight *Plagus macaques*. [REDACTED] do not know when the study started or if it was going.

[REDACTED] on [REDACTED] study [REDACTED] ask that [REDACTED] investigate the deaths of primates in this study as circumstances surrounding primate 3F008 (see [REDACTED]) to see if she was treated appropriately with vet care or [REDACTED] Asia. In addition, [REDACTED] a primate with a broken arm would be used in [REDACTED] icology study requires restraint, we ask that you investigate the [REDACTED] to ensure that the [REDACTED] - if it existed - was properly healed [REDACTED] the primate [REDACTED]

[REDACTED] are all concerned about two primates who died during the study (See Dec [REDACTED] description of [REDACTED] statement below) [REDACTED] who [REDACTED] died and the other who was reportedly found [REDACTED] after being dosed.

Were proper observations being conducted and [REDACTED] analyses performed to determine cause [REDACTED]

Further, HSUS investigator [REDACTED] comment [REDACTED] 3, 2021, conversation in which [REDACTED] recounts the [REDACTED] investigator tells coworkers that [REDACTED] (b) (6), (b) (7)(C) had [REDACTED] that the [REDACTED] (b) (6), (b) (7)(C) [REDACTED] the [REDACTED] this is an accurate representation of [REDACTED] (b) (6), (b) (7)(C) [REDACTED] (b) (6), (b) (7)(C) but it is disconcerting [REDACTED] that the lab [REDACTED] trust its clients to fully [REDACTED] use information concerning test [REDACTED] es.

The HSUS investigator first mentioned the study on [REDACTED], because one of the primates on study - [REDACTED] - [REDACTED] not eaten biscuits or [REDACTED] "multiple days." The investigator was told by coworker [REDACTED] (b) (6), (b) (7)(C) that [REDACTED] ate [REDACTED] hydrated. A [REDACTED] bowl of Gatorade had been put in her [REDACTED] ator's December [REDACTED] 21, log/video notes:

[REDACTED] not eaten for 3 days [REDACTED] at her bis [REDACTED] a b [REDACTED] Gatorade to aid in hydration. [REDACTED] (b) (6), (b) (7)(C) [REDACTED] strong with [REDACTED] monkey, 3F00 [REDACTED] tells me to feed her and that [REDACTED] very dehydrate [REDACTED]

[REDACTED] ove-mentioned primate's condition had not improved and [REDACTED] study had died the previ [REDACTED] do not [REDACTED] were euthanized. From [REDACTED] investigator's December 1 [REDACTED], [REDACTED] es:

[REDACTED] for monkey study 1718- [REDACTED] (b) (6), (b) (7)(C) restrained while [REDACTED] drew blood. I [REDACTED] study end [REDACTED] 546. I was told the study started [REDACTED] monkeys, 4 [REDACTED] and 4 [REDACTED] females. 2 monkeys died [REDACTED] group 2 male and 1 group 3 female. Today, one group 3 female, 3F008, was very [REDACTED] ing. 1718-21546 has two [REDACTED] articles, one is administered [REDACTED] administered immediately after the first [REDACTED] icle, for an hour, [REDACTED] how the two test [REDACTED] es interact with each other.

2021_INO_C006: Re [REDACTED] study 1718-21546, [REDACTED] (b) (6), (b) (7)(C) es, "[REDACTED] one die d [REDACTED] bl [REDACTED] w and then I came in the [REDACTED] y with one in full rigor [REDACTED]...Yes so we had a group 2 male and a group 3 female (he is talking about monkeys that [REDACTED] died), but [REDACTED] the group 3 female is still alive (referring to 3F008), doesn't m [REDACTED] fuc [REDACTED] sense to me. [REDACTED] letely health [REDACTED] le just [REDACTED] that [REDACTED] (b) (6), (b) (7)(C) [REDACTED] sponsor of one o [REDACTED] monkey [REDACTED] no [REDACTED] sp [REDACTED] as shady, and [REDACTED] (b) (6), (b) (7)(C) [REDACTED] sea those people suck. [REDACTED] draws blood, while I restrain. Monkey in [REDACTED] ending in 21103, with excess [REDACTED] al bruising. [REDACTED]



2021_INO_C0015: Monkey from study ending in 21546. Her eyes kept rolling back, and she acted very
in chair

2021_INO_C0015: Monkeys in chairs for IV infusion. [REDACTED] observe monkey 3F008 from study ending in

2021_INO_C0015: [REDACTED] draws blood from monkey 3F008, before IV infusion. Monkeys in chairs for IV infusion for
in 21546.

2021_INO_C0015: Monkey from study ending in 21546 with a broken arm. [REDACTED] tells me it happened before she came
lab. I say, "We [REDACTED] group 3 female [REDACTED] methods yes."

2021_INO_C0017: [REDACTED] asks if monkey 3F008 ate over the weekend, and [REDACTED] informs [REDACTED] the monkey was
use [REDACTED] the week (another monkey), insinuating no way to [REDACTED] gives the monkey
Gatorade via syringe.

2021_INO_C0022: Conv [REDACTED] reference to monkey 3F008. He references female monkey
3F008. [REDACTED] monkeys started in this crazy [REDACTED]
"We've [REDACTED] surprised we [REDACTED] her. And I attr [REDACTED]
[REDACTED] was not looking good [REDACTED] That's the first [REDACTED] I had seen her but she [REDACTED] rough."
[REDACTED] When I first got down here this afternoon she was hunched [REDACTED] sign. But she seems okay. We'll
me if [REDACTED] dead monkey...so be it."

Last date on which our [REDACTED] lived in this study was December 27, 2021, when they as [REDACTED] od

large APHIS to in [REDACTED] her, in cond [REDACTED] violat [REDACTED] implementing regulations [REDACTED]
[REDACTED] adequate guidance to [REDACTED] regarding eut [REDACTED]
[REDACTED] ing severe suffering, and the p [REDACTED] of ad [REDACTED] ary care [REDACTED]
[REDACTED] cause more than m [REDACTED] in or distress [REDACTED] animals
[REDACTED] attending [REDACTED] his or her [REDACTED] ee", 2.31(d)(1)(v) ("Animals
[REDACTED] that cannot [REDACTED] be p [REDACTED] euthanized...if
[REDACTED] are for anima [REDACTED] e available and provided as necessary
[REDACTED] I have an attending veterinarian who shall provide adequate
[REDACTED] lish and maintain progr [REDACTED] e
[REDACTED] appropriate methods [REDACTED] nt, control, diagnose. [REDACTED] at [REDACTED] d
[REDACTED] y, weekend, and holiday car [REDACTED] gu [REDACTED] to [REDACTED] involved in the care and

As mentioned [REDACTED] re sh [REDACTED] s for this primate study, but the number of deaths seems high considering only eight
(b) (6), (b) (7)(C) [REDACTED] looked at primate 3F008 [REDACTED] cember 13, 2021, it is
[REDACTED] and inappetence. Further [REDACTED] that primate [REDACTED] she have
[REDACTED] feel bowl? It may [REDACTED] bit amorphous a request on our part, but, could
[REDACTED] poss [REDACTED] ing to the sponsor, is shorthand for something more serious that has
[REDACTED] ed animal welfare in [REDACTED] labs?



bit VI

1690-21103 - violations of 9 C.F.R. 31(d), 2.33

dy was spon Nurix and used 52 primates v vage toxicity and toxicokinetic study with a
week recovery per began in mid-November, 2021 and just co in mid-March, 2022.

studies excess some swelling. Clinical observations throughout the
d bruising on faces and appendages, petechiae face and legs and scalp res.

December 23, 2021, the investigator's coworker, revealed that a Group female in the study had died "a couple
eks ago" from ad ulcers in he investigator asked the test
was for the Nurix study, did not know.

em 2021 cleaning the study room, the investigator with .25 ml of Baytril
lying on a countertop in the 1690-21103 stud may have been intended for prima 47
hind leg had a large The investigator believed the tissue was necrotic.

On December 29, 2021, an (b) (6), (b) (7)(C) asked a (b) (6), (b) (7)(C) "Why are you not killing this baby,"
ng 7. It is difficult to say if this was tiou not but v
ssmen to 5F047. From investigator's Dec

2021, INO C004: I discuss a monkey receiving baytril with not getting it anymore anyways
he he were all swollen up yesterday they said, um, w tril and watch her. I'm like she
literally has a necrotic spot on her leg."

Oh she's the one with

"That's been for weeks though. Why is this still going?"

"I don't know, ke' her. Pod

as and appeared sick. The HSU investigator to called (b) (6), (b) (7)(C)
(b) (6), (b) (7)(C) at the primate was e d not eat, had bruising and her
ur inves back primat be dosed - that she was not
ase holiday." A (b) (6), (b) (7)(C) primate two one of which w morphine. The
S investigator im the requested information and the
mate saying, "I'm so sorry lady, maybe this will be your last

ked at 5F048 but we don't er was e that between the
d the time when she wa lethargic before sing, she could
(b) (6), (b) (7)(C) e down to the primate again before giving ns that sh be
dosed.

is a humane endpoint id idied for this s may be that she

er primate in this stu appeared to have n not accord r in r, the veterinarian was
ified. The cause of the was unknown.

ncourage AP gate w t implementing reg ns
g fac which require rinary consultation, a ate guidance to personnel regarding
nasia decisions, timely eutha of animals exp severe suffering, and the provision of adequate veterinary



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(including appropriate diagnosis and treatment of injury), F.R. §§ 2.31(d)(1)(iv) ("Procedures that may cause more than momentary pain or distress to the animals will...involve, in their planning, consultation with the principal investigator or his or her designee"), 2.31(d)(1)(v) ("Animals that would otherwise experience severe or chronic pain or distress that cannot be alleviated shall be humanely euthanized, if appropriate, during the procedure"), 2.31(d)(1)(vii) ("Adequate veterinary care for animals shall be available and provided by a qualified veterinarian"), 2.33(a) ("Each research facility shall have an attending veterinarian who shall provide adequate veterinary care of its animals"), 2.33(b) ("Each research facility shall maintain a record of the use of appropriate veterinary care, including diagnosis and treatment of injury, and the availability of emergency, weekend, and after-hours care"), (4) Guidance to...personnel involved in the use of animals regarding euthanasia").





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2021_INO_C0018: (b) (6), (b) (7)(C) calls (b) (6), (b) (7)(C) tells him, (b) (6), (b) (7)(C) wanted to let you know the monkey's temperature registering (b) (6), (b) (7)(C) inside the Bair hugger, and she wants to know if we want to try out an IV. He looks real bad.

(b) (6), (b) (7)(C) the monkey in the Bair Hugger.

2021_INO_C0019: (b) (6), (b) (7)(C) about the monkey in the Bair Hugger. The Bair Hugger is for temperature management according to the label.

12.22.2021

(b) (6), (b) (7)(C) studying in (b) (6), (b) (7)(C) came to (b) (6), (b) (7)(C) Hall to do eye exams for rats in that study. I asked (b) (6), (b) (7)(C) monkey 4M015 in study 21506. He gave me a (b) (6), (b) (7)(C) down and told me that (b) (6), (b) (7)(C) to euthanize the monkey because they could not (b) (6), (b) (7)(C).

lunch I returned (b) (6), (b) (7)(C) for the next (b) (6), (b) (7)(C) I talked with (b) (6), (b) (7)(C) about the (b) (6), (b) (7)(C) in study 21506. She informed me 2 females died today, refer to video 12.22.2021_INO_C009.

2021_INO_C009: (b) (6), (b) (7)(C) waking up properly, and just freezing cold. (b) (6), (b) (7)(C) we got up from break, is we didn't get up from our first break...and (b) (6), (b) (7)(C) to start getting monkeys out, and (b) (6), (b) (7)(C) doesn't look good (b) (6), (b) (7)(C) watched it up and ran it back to her. And so it was cold, and so they put it in the Bair Hugger thing, and it's terrible (b) (6), (b) (7)(C) dropping, and dropping (b) (6), (b) (7)(C) dropping. Me: (b) (6), (b) (7)(C) said they could (b) (6), (b) (7)(C) temp, last (b) (6), (b) (7)(C). Yes (b) (6), (b) (7)(C) thing, yea, maybe I caught that (b) (6), (b) (7)(C) about (b) (6), (b) (7)(C) er." "So I'm (b) (6), (b) (7)(C) can do the ECG on a different day?" (b) (6), (b) (7)(C) ECG's are done...Until (b) (6), (b) (7)(C) of the study (b) (6), (b) (7)(C). Well I guess now we'll really know what it is."

12.23.2021

(b) (6), (b) (7)(C) on the day working with (b) (6), (b) (7)(C) in Building G, doing a cage change and sanitize room for (b) (6), (b) (7)(C). (b) (6), (b) (7)(C) told (b) (6), (b) (7)(C) and I that yesterday (b) (6), (b) (7)(C) male monkeys from study 1781-21506 [(b) (6), (b) (7)(C) 2402 12-wk oral (b) (6), (b) (7)(C)], died. He said one monkey had a low body temperature, and when placed in the Bair Hugger, her body temperature continued to decrease (b) (6), (b) (7)(C) animal care, (b) (6), (b) (7)(C) the study (b) (6), (b) (7)(C) two monkeys slated (b) (6), (b) (7)(C) study (b) (6), (b) (7)(C) (b) (6), (b) (7)(C) proceeded to tell (b) (6), (b) (7)(C) and I that (b) (6), (b) (7)(C) the (b) (6), (b) (7)(C) sponsor for study ending in 21 (b) (6), (b) (7)(C). On the (b) (6), (b) (7)(C) he was (b) (6), (b) (7)(C) resulting in the death (b) (6), (b) (7)(C) up animals, and (b) (6), (b) (7)(C) those deaths (b) (6), (b) (7)(C) both said (b) (6), (b) (7)(C) know if the (b) (6), (b) (7)(C) was ketamine (he/they (b) (6), (b) (7)(C) stated that the (b) (6), (b) (7)(C) did not tell (b) (6), (b) (7)(C) this (b) (6), (b) (7)(C) to video 12.23 (b) (6), (b) (7)(C) INO_C003). (b) (6), (b) (7)(C) as the replacement for the deceased male monkey) in study (b) (6), (b) (7)(C) drew blood. (b) (6), (b) (7)(C) study ending in 21506. (b) (6), (b) (7)(C) closed via oral gavage. (b) (6), (b) (7)(C) I (b) (6), (b) (7)(C) to be in normal condition, (b) (6), (b) (7)(C) on their inner legs (b) (6), (b) (7)(C) the previous two days. (b) (6), (b) (7)(C) if the test (b) (6), (b) (7)(C) is supposed to cause bruising (from (b) (6), (b) (7)(C) study 1 (b) (6), (b) (7)(C) 06). Monkey had (b) (6), (b) (7)(C) ve fa (b) (6), (b) (7)(C).

(b) (6), (b) (7)(C) like when they're sedated. It wasn't out (b) (6), (b) (7)(C)."

(b) (6), (b) (7)(C) "I don't (b) (6), (b) (7)(C) when they need to tell (b) (6), (b) (7)(C) that."

(b) (6), (b) (7)(C) "he was on that conference call...It wasn't them (referring to sponsor) that brought it to our attention, it was (b) (6), (b) (7)(C) one else. But (b) (6), (b) (7)(C) hey we see you've lost other high dose animals, and that (b) (6), (b) (7)(C) being on days they were (b) (6), (b) (7)(C) ed." Monkey (b) (6), (b) (7)(C).

2021_INO_C005: (b) (6), (b) (7)(C) draws blood while (b) (6), (b) (7)(C) restrains. Blood draw (b) (6), (b) (7)(C) monkeys female monkeys in study 1781-21506. The monkeys' legs are extremely bruised from (b) (6), (b) (7)(C) blood draws the previous day.



2021_INO_C006: [REDACTED] study [REDACTED] 1506, with [REDACTED] legs from multiple blood draws the previous day.

2021_INO [REDACTED] ...they're high dosed everyday,...sedated."

(b) (6), (b) (7)(C) [REDACTED] did?"

(b) (6), (b) (7)(C) [REDACTED] yea, so it's some [REDACTED] and sedation."

(b) (6), (b) (7)(C) [REDACTED] "So they didn't know that happened?"

(b) (6), (b) (7)(C) [REDACTED] said she assumed [REDACTED] was ketamine, but could have been a different

We encourage APHIS [REDACTED] ther, [REDACTED] notiv vic [REDACTED] ating regulations

[REDACTED] ac [REDACTED] which r [REDACTED] nary co [REDACTED] on, adequate guidance to personnel regarding

[REDACTED] ecisions, avoidance of unnecessary duplication [REDACTED] evious experiments, [REDACTED] uthanasia of animals

[REDACTED] ncing severe suffer [REDACTED] adequate veterinary care (including emergency ca [REDACTED] e 9 C.F.R. §§

(b) (6), (b) (7)(C) [REDACTED] (1)(iii) (approval requires "assurance that the [REDACTED] ies do not unnecessarily duplicate previous experiments");

(b) (6), (b) (7)(C) [REDACTED] (1)(iv) ("Pr [REDACTED] an momentary [REDACTED] to the animals [REDACTED] involve, in

[REDACTED] nning, consultation with [REDACTED] attending veterinarian or his or her designee"), 2.31(d)(1)(v) ("Animals that would

[REDACTED] wise [REDACTED] experience se [REDACTED] chronic pain or distress that cannot be relieved v [REDACTED] nlessly eu [REDACTED] d...if appropriate,

[REDACTED] the [REDACTED] ure") [REDACTED] i) ("Medical care for animals will be avail [REDACTED] necessary by a qualified

veterinarian"), 2.33(a) ("Each research facilit [REDACTED] an who shall provide adequate vete [REDACTED]

[REDACTED] animals"), 2.33(b) (" [REDACTED] lity shall establish and maintain programs of adequate veterinary care that

[REDACTED] e... (2) The use of appro [REDACTED] prevent, control, d [REDACTED] t r [REDACTED] ses and injuries, and the

availa [REDACTED] emergency, v [REDACTED] re... (4) C [REDACTED] sonnel involved in the care and [REDACTED] of animals

[REDACTED] ng

[REDACTED] e of these conversations as if Inoti [REDACTED] d have done a much mor [REDACTED] ough job of gathering data on
[REDACTED] had happened previously with the same test article. We w [REDACTED] S's determination as to whether
[REDACTED] dy h [REDACTED] n previously conducted with [REDACTED] results due to [REDACTED] information was imparted to
the veterinarian and study director.



bit VIII

1281-20359 - violations of 9 C.F.R. § 1.31(d), 2.32, 2.33

dy used 62 n in a nine-month dermal toxic study to Biopharma.

Our requests for APHIS study mini-pig leg may have been injured when a on the animal trying to restrain him.

December 8, 2021, the HSUS investigator was paid the blood draws on the animals used in this study. Two injured were mentioned investigator and

the conversation about (uncertain i.d. number but we believe it is 5M024) injured above the leg had been the investigator multiple techs" that a supervisor named (b) (6), (b) (7)(C) on the pig to restrain the animal and had injured the pig's hind leg. If the incident was addressed in a December 1, vet who wrote: "5F057 had this morning due to a lameness that had persisted since yesterday. During a TK collection, upon right distal hind limb and was noted as well as a likely fracture of the mid-tibia. S for necropsy evaluation, deep palpation, er

investigator was also told by (b) (6), (b) (7)(C) that mini-pig 7 was injured on December 2021, when another worker, handled the animal aggressively while getting the pig out (b) (6), (b) (7)(C) claimed that 5F057's foot had the cage and that her leg had broken when she net cage. The pig was not radiographed because she was scheduled to be euthanized later. 12/3/2021 records show an entry about animal: "5F057 hind left stuck in the grating of the metabolism, upon removing from urine collection Dec 3, 2021."

December 8, 2021, vet wrote 5F057 treated by the attending veterinarian for on an anti-inflammatory improved he is toe touching today and some v not. She was scheduled for necropsy to diagnostics and treatment were not

not seen by the veterinarian until December 8, one day decision on whether this animal was provided with

December 6, and assessed by the veterinarian. No further animal's upcoming euthanasia. Associate APHIS determining if it is 5M024 scheduled for necropsy soon after death." The investigator veterinary assessment animal most likely had a fracture of the mid-tibia which would be a painful condition that euthanasia date for 5M024

laboratory is going to continue using pigs in studies. The blood draws se an tried for minutes to hit jugular veins without success while multiple people lined the screaming

trying out the procedure appears to have violated AWA implementing regulations govern research facilities, which are advance veterinary consultation to and immobilization animals, with an experiencing severe, proper training for employees conducting procedures, the provision of adequate veterinary care including appropriate diagnosis and treatment of injuries). See 9 C.F.R. §§



d)(1)(iv) ("Procedures may...an moment...slight pain or distress to the animals will...involve, in planning, c...the attending veterinarian or his or her designee"), 2.31(d)(1)(v) ("Animals that would...severe or chronic pain or distress...cannot be relieved will be painlessly euthanized...if appropriate, the procedure"),...conducting procedures...will be appropriately qualified and trained in...procedures"),...1)(vii) ("Medical care for an...and provided as necessary by a qualified...arian"), 2.32(c) (...training and instruction of personnel must...Proper handling and care for the various species of animals use...2.33...shall have...veterinarian who shall...of...("Each...facility shall establish and maintain programs of...primary care that include... (2) The use of appropriate methods to prevent...control, diagnose, and treat diseases...ries...(4) Guidance...care and use of animals regarding handling [a...ilization...").



bit IX

ativ not Related to Specific Studie

Deaths from Hanging in Restraint Chairs

21 [REDACTED] US in [REDACTED] were w [REDACTED] in the Clean Hall area of the lab when a coworker, (b) (6), (b) (7)(C) joined them. He told his coworkers that he [REDACTED] responsible for a p [REDACTED] in quarantine who had choked to death in a restraint chair. (b) (6), (b) (7)(C) is a seemingly diligent and caring individual, and [REDACTED] was upset by the primate's death which he attributed to his having to [REDACTED] between studies due to [REDACTED] lack of staff.

The investigator's log/video [REDACTED] of November 30, 2021:

021 [REDACTED] C0020 (b) (6), (b) (7)(C) talking about a monkey in quarantine th [REDACTED] while in a restraint chair.

TRANSCRIPTION:

[REDACTED] was it just holding [REDACTED] do?"

[REDACTED] "Not the younger ones. [REDACTED] struggle with it...th [REDACTED] ch l [REDACTED] s."

Me: "

[REDACTED] a report on it."

[REDACTED] "Was t [REDACTED] b [REDACTED] bom."

[REDACTED] Oh, that's right. You said that."

On March 11, 2022, another primate was hung in a [REDACTED] re show details because the investigator [REDACTED] from someone rather than [REDACTED] being told about it directly b [REDACTED] people involved. The H [REDACTED] ly [REDACTED] during cage change [REDACTED] and the two individuals involved were (b) (6), (b) (7)(C) (last name [REDACTED] own). The investigator was told the primate who w [REDACTED] ing, was located in the "stock" room.

low restraint chairs

and so w [REDACTED] at

rd [REDACTED] t Inotiv. According to the HSU [REDACTED] investigator [REDACTED] which hou [REDACTED]

is. The primates mu [REDACTED] tstraint chairs i [REDACTED] hallway during

standing and [REDACTED] to

left una [REDACTED]

stitute violati [REDACTED] AWA regulations governing research facilities, which require adequate staffing to comply with the

or employees conducting [REDACTED] See 9 C.F.R.

personnel must include [REDACTED] handling and care for [REDACTED] rid [REDACTED] of

Each research facility shall [REDACTED] ar [REDACTED] tability of appropriate

ices to comply with th [REDACTED] chapter...[and]" [REDACTED] nance to principal

nd in the [REDACTED] use of animals regarding handlin [REDACTED] mmobiliza [REDACTED] 3.85

("Every perso [REDACTED] t [REDACTED] Welfare regulations...maintaining nonhuman primates must have enough employees to [REDACTED] his subpart") (emphases [REDACTED]).

January 9, 2022, the HS [REDACTED] stigator and a cowo [REDACTED] ned [REDACTED] were app [REDACTED] by [REDACTED] (b) (6), (b) (7)(C) a worker in animal [REDACTED] who said he had found a [REDACTED] sponsive primate in the "stock" room. The animal's USDA number was 202780. The

stigator and [REDACTED] the primate who was limp and cold and had many scabs [REDACTED] body. [REDACTED] this was a Sunday, a

technician, [REDACTED] to call (b) (6), (b) (7)(C) to [REDACTED] (b) (6), (b) (7)(C) said he would dr [REDACTED] but

d [REDACTED] to c [REDACTED] f the primate [REDACTED] he could get there. W [REDACTED] our investigator asked after the location

the Bair Hugger so they could u [REDACTED] n the primate, [REDACTED] remarked that it was in the enrichment room but that there



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no bags for it since [REDACTED] I believe [REDACTED] primate [REDACTED] died from hypothermia in study 21506. The investigator and [REDACTED] conducted by Andrew to put the primate back in the cage so they could get on to their next [REDACTED] a heat lamp and shone it on the primate after putting him back in his cage. They were told over lunch that [REDACTED] primate had been euthanized [REDACTED] not found anything of significance to explain the animal's death.

On March 17, 2022, the [REDACTED] investigator was informed by a coworker [REDACTED] that a "stock" primate had died that day in building N. We know [REDACTED] it this [REDACTED] case, or the [REDACTED] identification number.

[REDACTED] the APHIS to review the records for these primates to determine if thorough autopsies were conducted. We [REDACTED] that APHIS determine [REDACTED] primate 202780 earlier is due to an inadequate [REDACTED] number of [REDACTED] yeas. See 9 C.F.R. §§ 2.33(b)(1), 3.85.

Prolapses in Primates

Two [REDACTED] during the [REDACTED], the HSUS investigator reported primate [REDACTED] prolapses. The investigator reports that these two prolapses [REDACTED] apologize for the absence of animal [REDACTED]

From [REDACTED] investigator's log [REDACTED]

On [REDACTED] 2 [REDACTED] I was cleaning N, I found [REDACTED] monkey with [REDACTED] prolapsed rectum. I alerted [REDACTED] a senior tech, and he reinserted [REDACTED] rectum. The rectum prolapsed a second time, and he reinserted [REDACTED] the monkey back in the cage. [REDACTED] told [REDACTED] that this happens often because [REDACTED] monkeys become [REDACTED] again the monkey may fix it himself and reabsorb the prolapse.

2021_INO_C0010: I did [REDACTED] with a prolapsed rectum. I get [REDACTED] from another room and [REDACTED] the [REDACTED]

2021_INO_C0011: continuation of previous video. [REDACTED] puts prolapsed rectum back in.

2021_INO_C0 [REDACTED] he out again [REDACTED] push [REDACTED] then puts the prolapse [REDACTED]

[REDACTED] quarantined [REDACTED] monkey [REDACTED] 690-22023. One male [REDACTED] I alerted [REDACTED] who said she would [REDACTED] or call vet [REDACTED] an hour later, [REDACTED] a vet tech, came to the room and [REDACTED] the cage, and through the cage used her fingers to reinsert the [REDACTED]

[REDACTED] prolapse (in quarantine room [REDACTED] tel [REDACTED] staff will come. [REDACTED] repair the prolapse. I [REDACTED] phone and note [REDACTED] been 50 [REDACTED] g me she [REDACTED] the prolapse.

[REDACTED] primates should always be [REDACTED] recorded in observations, 2) [REDACTED] on. The FDA vet also said [REDACTED] the underlying [REDACTED] of a prolapse [REDACTED] that neither [REDACTED] was cleaned prior to reinsertion.

[REDACTED] encourage APHIS to inquire whether these incidents [REDACTED] violations [REDACTED] are [REDACTED] governing research [REDACTED] es, which require providing [REDACTED] adequate veterinary care, including appropriate treatment of injuries and timely [REDACTED] of animal [REDACTED] issues. See 9 C.F.R. § 2.33(b)(2)-(3).

[REDACTED] web [REDACTED] mer [REDACTED] Reporting [REDACTED] Welfare Issues





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2021_INO_ [REDACTED] coming out of the drain, filling the drain trough. The ceiling also has a patch from the

[REDACTED] falling in

2021_INO_CO [REDACTED] rats for study 1734-21400. [REDACTED] blood via tail vein while the rats are in
[REDACTED] ts.

I comment on how it is [REDACTED] side. [REDACTED]

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

[REDACTED] er [REDACTED] ch of [REDACTED]

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

[REDACTED] whole facility floods. This place can't handle [REDACTED] when it rains around h [REDACTED] ings fall in.."

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

[REDACTED] onder if that's w [REDACTED] erring to Clean Hall room B106).

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

"I know."

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

[REDACTED] then describ [REDACTED] room (Building B [REDACTED])

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

[REDACTED] then describes a previous [REDACTED] in Building N (immediately after completion of building).