ANIMAL WELFARE COMPLAINT

Complaint No.	Date Entered:	Processed By:
AC20-145	21-Feb-20	AVB

Referred To:	Reply Due:
Hallberg / Snow	24-Mar-20

Facility or Person Complaint Filed Against

Name:	Customer No.:	License No.:
Oregon Health & Science University	1046	92-R-0001

Address:	Email Address:
3181 SW Sam Jackson Park Rd	

City:	State:	Phone No.:
Portland	OR	(503) 494-1085

Complainant Information

Name:	Organization:
(b) (6), (b) (7)(C), (b) (7)(D)	[redacted]

Address:	Email Address:
(b) (6), (b) (7)(C), (b) (7)(D)	(b) (6), (b) (7)(C), (b) (7)(D)

City:	State:	Phone No.:
[redacted]	[redacted]	(b) (6), (b) (7)(C), (b) (7)(D)

How was the Complaint received?
Email

Details of Complaint:
SEE ATTACHED

Results:
This complaint is based entirely on citations issued. There is no new information.

Please close.

Application Kit Provided:
Yes: ☐ No: ☒

Inspector:	Date:
Gwynn M. Hallberg	21-Feb-20

Reviewed By:	Date:
Carolyn J McKinnie, DVM, SVMO	27-Feb-20

USDA

United States Department of Agriculture

February 21, 2020

Animal and Plant Health Inspection Service

Animal Care
4700 River Road
Riverdale, MD
20737

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

Dear Complainant:

Thank you for your corresopondence dated 18-Feb-20. We are reviewing your concerns and assigned tracking number AC20-145. 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 publically 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. U.S. 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

Betty Goldentyer
Deputy Administrator
Animal Care

Benson, Amy V - APHIS

From: (b) (6), (b) (7)(C), (b) (7)(D)
Sent: Tuesday, February 18, 2020 4:21 PM
To: Gibbens, Robert - APHIS
Cc: APHIS-AnimalCare
Subject: Federal Complaint -- OHSU

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

Dr. Robert Gibbens
2/18/20
Director, Western Region, USDA/APHIS/AC,
2150 Center Ave.
Building B, Mailstop 3W11
Fort Collins, CO 80526-8117

Dr. Gibbens,

I am writing to you today to file, yet another, Official Complaint against the Oregon Health and Science University (OHSU - 92-R-0001), for clear, and disgusting, violations of the Animal Welfare Act.

In roughly 3 years OHSU has now amassed a total of 18 non-compliances, 2 of which are DIRECT (even more rare and serious than CRITICAL), and 7 of which are considered to be CRITICAL. During this time period OHSU negligence has killed 13 animals, seriously injured three more, denied water to many, denied veterinary treatment to many, failed to follow proper practices for sterile surgery multiple times, failed to follow proper research practices by using a monkey in a second surgical procedure, used unapproved drugs, and failed to follow approved protocols. All of these incidents follow an Official Warning which was issued to OHSU for the strangulation death of a monkey. It would be shorter to list the few things that OHSU has done correctly.

As you know, OHSU's most recent inspection was on 1/21/20 The first citation in this inspection is a REPEAT citation for unqualified personnel. It states:

"2.32 PERSONNEL QUALIFICATIONS At the time of inspection, a ferret was undergoing a survival procedure involving an open craniotomy chamber exposing the brain cavity (major operative procedure). The procedure involved placing study devices inside the chamber. The placement of the sterile field for instruments and supplies was in a location where it could be easily contaminated, unobserved by the person doing the procedure. During the observation, the sterile field was on an instrument table in a corner of the very small room outfitted as an acoustic chamber. As the person manipulated the electrode and fiber optic cables, the sterile field was at times behind him, allowing his lab coat to breach sterility of the field."

This incident sounds very much like a repeat of the incident discussed in the 6/3/19 inspection (listed below) which also discusses non-sterile surgical methods. Apparently the staff of OHSU still has no clue how to properly conduct surgery on animals. If this had happened within a veterinary clinic, all of the staff would have been fired.

This same inspection also cites OHSU for failure to comply with requirements for proper veterinary care, including inadequate observation of animals, this is a CRITICAL REPEAT citation for violating:

"2.33(b)(3) ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE
An incident occurred recently when an employee needed to leave before completing care for one room of prairie voles. Another employee completed the work in that room for the day. The next day, four animals in that room were found dead and another was moribund and euthanized. The facility determined that cage change and water bottle replacement for a section of the animal area was missed during the change of employees. Due to the lack of that day's observation for these animals, their water ran out, resulting in dehydration and death."

In other words, OHSU staff are so utterly inept that they cannot ascertain whether or not animals have adequate access to water. This is unconscionable.

This report also contains a non-compliance for failing to file OHSU's annual report properly. This is a failure to comply with ***2.36(b)(3) ANNUAL REPORT***.

The next most recent inspection of OHSU occurred on 6/3/19. The first citation in this inspection is for unqualified personnel. It states:

"2.32 PERSONNEL QUALIFICATIONS.
A lab group was found on April 2, 2019 to be conducting a surgery with poor sterile technique. Department of Comparative Medicine (DCM) veterinarians and technicians in attendance stepped in to ensure the welfare of the ferret. This pilot surgery ran into unexpected anatomical complications, and the animal was euthanized under anesthesia. The materials and methods for this euthanasia were not on the approved protocol. The lab's training records were not current prior to the incident – copies provided were back-filled with training information and dates after the deficiencies in the lab were noted in April. The IACUC did not have personnel qualification information available at the time the protocol was approved."

It is very clear that these people should never have been permitted to perform surgical procedures (or for that matter, even touch an animal), because the IACUC who approved this protocol had no proof that the people listed on the protocol were adequately trained to perform that protocol. The OHSU research administration knowingly allowed unqualified personnel to be involved in this project. These results should not be a surprise to anyone.

The next citation (DIRECT) in this 6/3/19 inspection was for inadequate veterinary care:

"2.33(b)(2) DIRECT ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.
In the same lab, there were containers of dressing supplies used for ferret cap care on the bench. The containers appeared dirty, and had large areas of corrosion on the lids and under the lid. The containers held gauze for cleaning and non-stick pads for dressing the caps. Corroded metal cannot be adequately cleaned, disinfected, or sterilized. Their use is not appropriate for procedures requiring clean or sterile technique because they can harbor pathogens which may result in infection."

The next citation (DIRECT) this inspection was also for inadequate veterinary care:

"2.33(b)(3) DIRECT ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.
At the time of inspection, the same lab had a ferret (#100951) in a restraint for training and cap care. The ferret had a strong foul odor, and the cap margins were moist with crusty exudate. A second ferret (#270877B) in a holding cage was rubbing its head cap on the fabric of a hammock. Review of the protocol revealed that rubbing or itching of the surgery site will trigger notification to the DCM. Neither animal had been reported to the AV in the DCM."

I have to say that I am positively repulsed by the information in this citation. I am compelled to restate this: "***The ferret had a strong foul odor, and the cap margins were moist with crusty exudate."***

How is it possible that this was allowed to happen in a facility that has fulltime veterinarians on hand? the level of negligence depicted here is nothing short of astonishing. The reaction to this text is strong and visceral. After reading this I feel ill.

I am disappointed that the USDA inspector, who was quite right to issue Direct citations, did not confiscate these animals. They were clearly in danger from the systemic negligence which is underway at OHSU.

Instead of re-iterating our previous complaint, which discusses USDA reports from 2017 - 2018, and other documents, I will simply refer you to our complaint from January of 2019, which is posted here: https://saenonline.org/news-media-news-2019/Oregon-Health-&-Science-University-Official-Complaint-1-14-19.pdf

Over the last several years OHSU has amassed 18 non-compliance citations. There have been multiple citations for inadequate veterinary care, unqualified personnel, improper animal handling, inadequate supervision of experimentation by the OHSU IACUC. The violations are so varied and pervasive that it is obviously not one lab, or even researchers using one species -- as the citations have been relevant to monkeys, ferrets, and other species.

OHSU clearly has clearly demonstrated contempt for federal supervision and has not taken USDA/APHIS/AC's previous enforcement actions seriously. The health and well-being of animals is being ignored, and as a result animals continue to be sickened, injured, and killed as a direct result of OHSU carelessness. Not only that, but the most basic scientific procedures, such as performing aseptic surgery, are being ignored, REPEATEDLY! Therefore, I strongly urge you to impose the maximum penalty on OHSU, because it has become extremely clear that your previous efforts at enforcement actions (issuance of ***"Official Warnings"*** in 2016 and 2014) have been ignored.

OHSU clearly believes that they are above the law. This facility must be clearly and severely punished, otherwise you might as well perform no further inspections. As things currently stand this lab is demonstrating to the rest of the research community that it is possible to repeatedly violate federal regulations with impunity. OHSU has clearly and undeniably violated the Animal Welfare Act again and again. Again, animals have been sickened, injured, and killed. None of this is in doubt.

YOU MUST NOW DO SOMETHING ABOUT IT!!! I must strongly urge that your office suspend all ferret projects at OHSU and confiscate the animals. Otherwise, the next time that your inspector returns, there will most certainly be fewer living ferrets at OHSU. And if more ferrets die due to OHSU negligence, their blood will be on your hands.

Therefore, I hereby file an Official Complaint against the Oregon Health and Sciences University relevant to the deaths and injuries to multiple animals. I must insist that your office institute an immediate investigation.

I know that your office considers major violations of the Animal Welfare Act to be very serious in nature, especially when these violations kill, abuse, or seriously injure animals. Since the Oregon Health and Sciences University has a long history of animal abuse which has led to multiple animal deaths and injuries, I must insist that you take the most severe action allowable under the Animal Welfare Act and immediately begin the process of issuing the maximum fine allowable against the Oregon Health and Sciences University at the completion of your investigation -- $10,000 per infraction, per animal. As I am sure you are aware, this could result in a six-figure penalty.
I look forward to hearing from you in the near future about the fate of this facility.

Sincerely,

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

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

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

Attachments: 2 USDA Inspection Reports

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

United States Department of Agriculture
Animal and Plant Health Inspection Service

GHALLBERG

2016082569707799 Insp_id

Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 001
OREGON HEALTH & SCIENCE UNIV.

Type: ROUTINE INSPECTION
Date: 21-JAN-2020

2.32(c)(1)(iv) **REPEAT**

PERSONNEL QUALIFICATIONS.

At the time of inspection, a ferret was undergoing a survival procedure involving an open craniotomy chamber exposing the brain cavity (major operative procedure). The procedure involved placing study devices inside the chamber. The placement of the sterile field for instruments and supplies was in a location where it could be easily contaminated, unobserved by the person doing the procedure. During the observation, the sterile field was on an instrument table in a corner of the very small room outfitted as an acoustic chamber. As the person manipulated the electrode and fiber optic cables, the sterile field was at times behind him, allowing his lab coat to breach sterility of the field.
Aseptic technique requires that sterile fields be maintained the entire time a body cavity is open. Failure to do so may result in infection, harming the animal and interfering with the research.
From this point forward, ensure that all sterile fields remain sterile for the duration of any procedure involving an open body cavity.

2.33(b)(3) **CRITICAL** **REPEAT**

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

An incident occurred recently when an employee needed to leave before completing care for one room of prairie voles. Another employee completed the work in that room for the day. The next day, four animals in that room were found dead and another was moribund and euthanized. The facility determined that cage change and water bottle replacement for a section of the animal area was missed during the change of employees. Due to the lack of that day's observation for these animals, their water ran out, resulting in dehydration and death.
All animals must be observed daily to assess their health and any needs they may have.
Corrected prior to the time of inspection by revising the communication and transition procedure for a staff change during the workday.

Prepared By: [redacted]
HALLBERG GWYNN, D V M USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER 5036
Date: 27-JAN-2020

Received By: [redacted]
Title:
Date: 27-JAN-2020

Inspection Report

2.36(b)(3)

ANNUAL REPORT.

The IACUC approved exceptions to the requirement for a dedicated surgery area for non-rodent animals for protocols IP01561 and IP00211. These exceptions were not reported on the 2019 annual report.
All granted exceptions not specifically allowed in the regulations must be reported on the annual report.
Correct within 30 days by submitting an amended report to USDA.

This inspection was conducted on January 21-23, 2020 with facility personnel, and the exit interview was conducted with the IACUC Director on January 23, 2020.

Prepared By: [redacted]
HALLBERG GWYNN, D V M USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER 5036
Date: 27-JAN-2020

Received By: [redacted]
Title:
Date: 27-JAN-2020

United States Department of Agriculture
Animal and Plant Health Inspection Service

Inspection Report

Oregon Health & Science University
3181 S W Sam Jackson Park Rd., #L335
Portland, OR 97239

Customer ID: **1046**
Certificate: **92-R-0001**
Site: 001
OREGON HEALTH & SCIENCE UNIV.

Type: ROUTINE INSPECTION
Date: 03-JUN-2019

2.32

PERSONNEL QUALIFICATIONS.

A lab group was found on April 2, 2019 to be conducting a surgery with poor sterile technique. Department of Comparative Medicine (DCM) veterinarians and technicians in attendance stepped in to ensure the welfare of the ferret. This pilot surgery ran into unexpected anatomical complications, and the animal was euthanized under anesthesia. The materials and methods for this euthanasia were not on the approved protocol.
The lab's training records were not current prior to the incident – copies provided were back-filled with training information and dates after the deficiencies in the lab were noted in April. The IACUC did not have personnel qualification information available at the time the protocol was approved.
The mitigation plan included a training covering scrubbing and gowning on 5/21/19. Two of the people in that training under the lab's protocol number are not listed as personnel on the approved protocol. It is unclear if they have participated in procedures.
The IACUC must evaluate qualifications of all personnel on the protocol, and ensure all personnel are listed on the protocol, as part of the approval process.
Correct by ensuring all aspects of Section 2.32 are met prior to approving protocols from this point forward.

2.33(b)(2) **DIRECT**

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

In the same lab, there were containers of dressing supplies used for ferret cap care on the bench. The containers appeared dirty, and had large areas of corrosion on the lids and under the lid. The containers held gauze for cleaning and non-stick pads for dressing the caps.
Corroded metal cannot be adequately cleaned, disinfected, or sterilized. Their use is not appropriate for procedures requiring clean or sterile technique because they can harbor pathogens which may result in infection.
Correct by using containers able to be properly cleaned and disinfected or sterilized from this point forward.

Prepared By: [redacted]
HALLBERG GWYNN, D V M USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER 5036
Date: 11-JUN-2019

Received By: [redacted]
Title:
Date: 11-JUN-2019

2.33(b)(3) DIRECT

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

At the time of inspection, the same lab had a ferret (#100951) in a restraint for training and cap care. The ferret had a strong foul odor, and the cap margins were moist with crusty exudate. A second ferret (#270877B) in a holding cage was rubbing its head cap on the fabric of a hammock. Review of the protocol revealed that rubbing or itching of the surgery site will trigger notification to the DCM. Neither animal had been reported to the AV in the DCM. Both animals were immediately examined by DCM veterinarians and a treatment plan was initiated.
Correct by ensuring that, from this point forward, all animal use personnel are aware of the daily observation requirements in this section, and that they know that they must immediately report problems to the Attending Veterinarian.

This inspection and exit interview were conducted on June 3, 4, and 6, 2019 with facility personnel.

Prepared By: [redacted]
HALLBERG GWYNN, D V M USDA, APHIS, Animal Care
Date: 11-JUN-2019

Title: VETERINARY MEDICAL OFFICER 5036

Received By: [redacted]

Title:

Date: 11-JUN-2019