



USDA-APHIS-Animal Care



ANIMAL WELFARE COMPLAINT		
Complaint No. AC19-189	Date Entered: 25-Mar-19	Processed By: SSE
Referred To: Sime/Hovancsak		Reply Due: 26-Apr-19
Facility or Person Complaint Filed Against		
Name: Mayo Clinic	Customer No.: 542	License No.: 41-R-006
Address: 1997 GUGGENHEIM 200 FIRST ST SW		Email Address:
City: ROCHESTER	State: MN	Phone No.: (507) 284-1050
Complainant Information		
Name: (b) (6), (b) (7)(C), (b) (7)(D)	Organization:	
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: The complaint has three concerns: 1. Justification of animal use is insufficient because alternatives exist. 2. The use of animals for Emergency Medicine Training is not "Unavoidable". 3. The facility's IACUC is failing to properly oversee animal use. A focused inspection of May Clinic, CID #542 Registration 41-R-0006, was completed on 25 March 2019. The inspection included review of records and discussion with the IACUC Coordinator. Two Protocols involving animal use were reviewed. In response to Issue 1 (Justification of animals is insufficient because alternatives exist) and Issue 2 (The use of animals for Emergency Medicine Training is not "Unavoidable"): The scientific objective of one protocol is to provide a course involving many emergency scenarios to train residents to become proficient in performing various emergency pediatric medical procedures. The principal investigator provided a rationale for involving animals. The principal investigator also considered alternatives and included a rationale for not using alternatives. The IACUC reviewed and approved this protocol. The scientific objective of the second protocol is also to train resident physicians. The principle investigator provided a rationale for involving animals. The principle investigator also provided a		

11 APR 2019



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written narrative considering alternatives and a rationale for not using those alternatives. The IACUC reviewed and approved this protocol.

The regulatory requirement to search for and consider alternatives was met. There is no regulatory requirement to adopt alternatives if they are found. The fact that alternatives may exist does not mean that they are suitable for the purposes of the teaching or research being conducted.

In response to issue 3 (The IACUC is failing to properly oversee animal use):

Both Protocols were reviewed and approved by full committee review. Both protocols contained all the components required by regulations and were properly reviewed and approved by a valid IACUC.

This focused inspection found no concerns regarding the issues stated in the complaint. No noncompliances of the AWA were noted and no further action is necessary.

Application Kit Provided:

Yes: ☐

No: ☒

Inspector:

Debra Sime, DVM

Date:

3-Apr-19

Reviewed By:

Date:

11 APR 2019



Animal and Plant
Health Inspection
Service

Animal Care
Western Region

March 25, 2019

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

Dear Complainant:

Thank you for your correspondence dated 20-Feb-19 concerning Mayo Clinic. Your complaint has been issued number AC19-189. **Depending on the circumstances of the situation, please allow us enough time (30 to 60 days) to thoroughly look into your concerns.** After that time, the status of our findings may be requested through the Freedom of Information Act (FOIA) office.

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

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

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

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

Sincerely,

Bernadette Juarez
Deputy Administrator
USDA APHIS Animal Care

From: [Whisenton, Katie M](#)
To: [Ennis, Sari - APHIS](#)
Subject: FW: APHIS complaint: Mayo Clinic College of Medicine and Science
Date: Monday, March 25, 2019 9:02:28 AM
Attachments: [image003.png](#)
[image004.png](#)
[image001.png](#)
Importance: High

Hey Sari-

This may be in the group of emails I sent to the other day but will you please process this complaint ASAP. ☺ Let me know if you have any questions or need anything else.

Thanks,

Katie Whisenton

Supervisory Inspection & Licensing
Program Specialist
Desk: 970-494-7587
Cell: 970-342-3604

USDA-APHIS-AC
2150 Centre Ave.
Building B, 3W11
Fort Collins, CO 80526
ph:970-494-7478
fax:970-494-7461

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From: Kingston, Susan K - APHIS
Sent: Monday, March 25, 2019 8:54 AM
To: Whisenton, Katie M <Katie.M.Whisenton@aphis.usda.gov>
Cc: Sime, Debra M - APHIS <Debra.M.Sime@aphis.usda.gov>
Subject: FW: APHIS complaint: Mayo Clinic College of Medicine and Science
Importance: High

Hi Katie,

I'm sorry to pester you, but (b) (6), (b) (7)(C) tomorrow and needs to get this complaint so she can get it completed. Would you please have someone log it and send it to her and Dr. Hovancsak?

Thanks,
Susan

Susan Kingston DVM MS
USDA APHIS AC
Supervisory Animal Care Specialist
240-308-2457

From: Kingston, Susan K - APHIS
Sent: Thursday, March 21, 2019 12:42 PM
To: Whisenton, Katie M <Katie.M.Whisenton@aphis.usda.gov>
Subject: FW: APHIS complaint: Mayo Clinic College of Medicine and Science
Importance: High

Hi Katie,

Do you know if the complaint below has been logged yet? Actually, what we need is to have it logged and sent to the inspector (Deb Sime) and SACS (Cathy Hovancsak) as soon as possible. (b) (6), (b) (7)(C), but she knows this complaint is coming, and she would like to address it prior to (b) (6), (b) (7)(C).

Cathy Hovancsak is on leave, and I'm covering her team for her, which is why I am involved.

If you have any questions, let me know. Thank you!
Susan

Susan Kingston DVM MS
USDA APHIS AC
Supervisory Animal Care Specialist
240-308-2457

From: Sime, Debra M - APHIS
Sent: Thursday, March 21, 2019 11:45 AM
To: Kingston, Susan K - APHIS <Susan.K.Kingston@aphis.usda.gov>
Subject: Fwd: APHIS complaint: Mayo Clinic College of Medicine and Science

Hi Susan,

If this helps, let me know.

Best regards,
Debra Sime, DVM
240-475-7124
Sent from my iPhone

From: Sime, Debra M - APHIS
Sent: Thursday, February 21, 2019 8:14:47 AM
To: Hovancsak, Catherine F - APHIS
Subject: RE: APHIS complaint: Mayo Clinic College of Medicine and Science

Thanks, I will let you know when I can fit it in. Looks like I need the complaint form sent to me. Deb



DEBRA SIME, DVM | VETERINARY MEDICAL OFFICER
USDA ■ APHIS ■ ANIMAL CARE | 920 Main Campus Drive Suite 200 Raleigh, NC 27606
☎ 240.475.7124 Mobile | ✉ debra.m.sime@usda.gov

From: Hovancsak, Catherine F - APHIS
Sent: Wednesday, February 20, 2019 8:45 AM
To: Sime, Debra M - APHIS <Debra.M.Sime@aphis.usda.gov>
Subject: FW: APHIS complaint: Mayo Clinic College of Medicine and Science

Just a heads up – we can discuss before you check on this.

Thanks,

Cathy

From: Gibbens, Robert - APHIS
Sent: Wednesday, February 20, 2019 8:42 AM
To: Theodorson, Elizabeth C - APHIS <Elizabeth.C.Theodorson@aphis.usda.gov>; Hovancsak, Catherine F - APHIS <Cathy.F.Hovancsak@aphis.usda.gov>; AC West <acwest@aphis.usda.gov>
Subject: FW: APHIS complaint: Mayo Clinic College of Medicine and Science

Complaint.

Robert M. Gibbens, DVM
Director, Animal Welfare Operations
USDA, APHIS, Animal Care
2150 Centre Avenue, Bldg. B
Ft. Collins, CO 80526
Phone: 970-494-7478
Fax: 970-472-9558



[Join the Animal Care Stakeholder Registry and receive emails on topics of interest](#)

From: (b) (6), (b) (7)(C), (b) (7)(D)
Sent: Wednesday, February 20, 2019 7:26 AM
To: Gibbens, Robert - APHIS <Robert.M.Gibbens@aphis.usda.gov>
Subject: APHIS complaint: Mayo Clinic College of Medicine and Science

Feb. 20, 2019

Robert Gibbens, D.V.M.
Director, Animal Welfare Operations
USDA/APHIS/Animal Care
2150 Centre Ave.
Building B, Mailstop 3W11
Fort Collins, CO 80526-8117

Dear Dr. Gibbens:

Attached (pdf) and pasted below (Word document) please find our complaint regarding the use of animals for emergency medicine procedural training at Mayo Clinic College of Medicine and Science in Minneapolis, Minn. Supporting documents are also attached.

Thank you for addressing our complaint.

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)

E-mail: (b) (6), (b) (7)(C), (b) (7)(D)

Feb. 20, 2019

Robert Gibbens, D.V.M.
Director, Animal Welfare Operations
USDA/APHIS/Animal Care
2150 Centre Ave.
Building B, Mailstop 3W11
Fort Collins, CO 80526-8117

Submitted by e-mail (Robert.M.Gibbens@aphis.usda.gov)

Re: Use of Live Animals for Emergency Medicine Residency Training at Mayo Clinic Rochester

Dear Dr. Gibbens:

The (b) (6), (b) (7)(C), (b) (7)(D) requests that the Animal and Plant Health Inspection Service (APHIS) investigate the use of live animals for training at Mayo Clinic College of Medicine and Science in Rochester, Minn. ("Mayo Clinic Rochester"). The college uses animals to teach procedures to emergency medicine residents, despite the widespread availability and implementation of nonanimal training methods that are both educationally and ethically superior.

The (b) (6), (b) (7)(C), (b) (7)(D) confirmed in early 2018 that emergency medicine residents participate in a yearly procedure lab using live animals. Since Mayo Clinic Rochester is a private university, it is exempt from state public records statutes. Thus, records regarding the animal-use protocol(s) and the procedures trained using animals are not available. However, below are some procedures commonly performed on live animals during emergency medicine residency training elsewhere, all of which have validated and widely implemented nonanimal options:

- Chest tube placement (an incision between the ribs followed by the insertion of a tube into the chest cavity to drain air, blood, or other fluids)
- Cricothyroidotomy (an incision in the throat and the insertion of a breathing tube)
- Open thoracotomy (an incision in the chest wall with insertion of a rib-spreader to expose the heart and lungs)
- Pericardiocentesis (the insertion of a needle below the breastbone to remove fluid from the sac surrounding the heart)

Mayo Clinic Rochester's animal use is at odds with the current standards of practice in emergency medicine training in the United States and Canada. According to an ongoing (b) (6), (b) (7)(C), (b) (7)(D) survey, 94 percent of emergency medicine residencies (252 of 267)—including top-ranked programs at the University of Southern California, the University of Cincinnati Medical Center, and Denver Health Medical Center—exclusively use nonanimal methods to train residents. In addition, the other emergency medicine residency programs in Minnesota—Hennepin Healthcare in Minneapolis and HealthPartners Institute Regions Hospital in St. Paul—use only human-based training methods.

Under the Animal Welfare Act, Mayo Clinic Rochester meets the statutory definition of a "research facility" and is therefore required to comply with the Animal Welfare Act.

As part of this required compliance, any use of live animals for research, testing, or training must be approved by the university's Institutional Animal Care and Use Committee (IACUC). Mayo Clinic Rochester is currently registered with the U.S. Department of Agriculture under cert. no. 41-R-0006.

The (b) (6), (b) (7)(C), (b) (7)(D) believes that inadequate oversight by the college's IACUC is responsible for the approval and ongoing use of live animals in its emergency medicine residency program. The specific regulatory violations are:

1. Justification of Animal Use is Insufficient Because Alternatives Exist

Section 2143 of the Animal Welfare Act and CFR Title 9, Section 2.31(d)(1)(i, ii) of the Animal Welfare Act's implementing regulations require that the principal investigator (PI)—including course instructors—consider alternatives to procedures that may cause more than momentary or slight pain or distress to any animal used for research or educational purposes.

In addition, the PI must provide a written narrative description of the methods and sources used to determine that alternatives were not available. The content of this narrative is detailed in the APHIS *Animal Care Policy Manual* (2011), which states in Policy 12: "If a database search or other source identifies a bona fide alternative method (one that could be used to accomplish the goals of the animal use proposal), the IACUC may and should ask the PI to explain why an alternative that had been found was not used."

We believe that the PI did not meet this requirement because justification of animal use for emergency medicine residency training is not possible in view of the validation and widespread implementation of purpose-designed nonanimal training methods. Having not provided objective evidence to support animal use in view of numerous acknowledged validated and implemented alternatives, this requirement of the Animal Welfare Act was not met.

A proper alternatives search would have revealed nonanimal methods for the training of emergency procedures and an abundance of peer-reviewed literature demonstrating the equivalence or superiority of simulation-based emergency medicine training compared to animal use. All emergency medicine procedural skills, including open thoracotomy, cricothyroidotomy, pericardiocentesis, chest tube placement, diagnostic peritoneal lavage, and cardiac pacing, can be taught using human-based medical simulation, partial task trainers, and human cadavers.

Over the last 15 years, animal use among surveyed emergency medicine residency programs has declined from 86 percent (Custalow 2004, published survey) to 6 percent (15 of 267 surveyed programs); see Addendum I. With advances in technology, as well as ethical considerations, there has been a paradigm shift, and a large majority of programs are now exclusively employing nonanimal training methods. For a summary of recent peer-reviewed publications and reviews pertaining to emergency medicine training methodologies, see Addendum II.

In addition, U.S. Air Force Maj. Andrew Hall, M.D., found in 2014 that post-training self-efficacy scores demonstrated no statistical difference between live animal and simulator training methods for chest tube placement, cricothyroidotomy, and diagnostic peritoneal lavage.^[1] In a letter to the editor published in *Military Medicine* the same year, Maj. Hall concluded: **"We have entered into an age where artificial simulator models are at least equivalent to, if not superior to, animal models."**^[2]

A recent study funded by the U.S. Army compared the physiological stress response of training with medical simulators versus live animals. The study, which was presented at the CHEST Annual Meeting on Oct. 10, 2018, in San Antonio, found that there were no significant differences for peak stress response between the two methods and determined that **"synthetic models can produce a stress response equivalent to that of live tissue during simulation training."**^[3]

A validated and widely implemented example of these human-based methods is Simulab's TraumaMan System, a realistic anatomical human body simulator with lifelike skin, subcutaneous fat, and muscle. The TraumaMan System can be used to replace the use of live animals for numerous procedures, including cricothyroidotomy, pericardiocentesis, chest tube placement, diagnostic peritoneal lavage, and intravenous cutdown. In fact, the TraumaMan System is used by a large number of Advanced Trauma Life Support programs to teach many of the skills commonly taught in emergency medicine residency procedural labs, and it is endorsed by the American College of Surgeons for trauma and surgery skills training.

Further, there are many other simulators that are used in emergency medicine residency training. Laerdal's SimMan 3G is an advanced patient simulator that can be used to teach cricothyroidotomy, chest tube placement, needle thoracostomy, cardiac pacing, and intraosseous catheter placement. In addition, the Emergency Thoracotomy Simulator by Operative Experience, Inc., can be used to teach open thoracotomy, aortic cross-clamping, and cardiac massage. Addendum III presents a sampling of key training devices available to replace animal use in Mayo Clinic Rochester's emergency medicine procedural training.

In addition, Mayo Clinic Rochester already has a state-of-the-art facility—the Multidisciplinary Simulation Center—which offers a range of high-fidelity mannequins and partial task trainers that could provide the simulation capabilities to replace the use of animals in the emergency medicine residency.

2. The Use of Animals for Emergency Medicine Training is Not “Unavoidable”

The Animal Welfare Act also requires that activities involving animals be designed to “assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research.” 9 C.F.R. § 2.31(e)(4).

We believe that this requirement was not met by the PI because of the widespread availability of validated simulators and the fact that 94 percent of surveyed emergency medicine programs in the United States and Canada do not use live animals. This clearly demonstrates that such use of live animals is not “unavoidable.”

3. Mayo Clinic Rochester's IACUC is Failing to Properly Oversee Animal Use

Section 2143 of the Animal Welfare Act and Title 9, Section 2.31(d)(1)(i, ii) of the Animal Welfare Act's implementing regulations require that the IACUC enforce the requirements described in items 1 and 2 above and thereby determine that the proposed activities are in accordance with the Animal Welfare Act and CFR Title 9, Section 2.31(d).

Further, the APHIS *Animal Care Policy Manual* (2011) Policy 12 places the burden of alternatives justification on the IACUC as well as the PI by stating: “The IACUC, in fact, can withhold approval of the study proposal if the Committee is not satisfied with the procedures the principal investigator plans to use in his study.”

We believe that these requirements were not met by Mayo Clinic Rochester's IACUC because the animal use protocol was approved despite the violations described in items 1 and 2 above. Thus, the (b) (6), (b) (7)(C), (b) (7)(D) alleges inadequate institutional oversight by Mayo Clinic Rochester's IACUC.

Accordingly, the (b) (6), (b) (7)(C), (b) (7)(D) requests that APHIS investigate this matter to find Mayo Clinic Rochester and its IACUC in violation of the Animal Welfare Act and its implementing regulations as detailed above, and order correction and appropriate penalties.

Thank you for your attention.

Sincerely,



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



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



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



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



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

Addendums

1. Animal Use in Allopathic and Osteopathic Emergency Medicine Residency Programs in the United States: An Ongoing Survey
2. Emergency Medicine Training References: Research and Reviews
3. Simulation for Emergency Medicine Residency Training: A Sampling of Key Devices

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- [1] Hall A., Riojas R., Sharon D. Comparison of self-efficacy and its improvement after artificial simulator or live animal model emergency procedure training. *Military Medicine*. 2014; 179(3):320-3.
- [2] Hall A. Letter to the Editor. *Military Medicine*. 2014; 179(7):697.
- [3] Keller J., Hart D., Rule G., Bonnett T., Sweet R. *The Physiologic Stress Response of Learners During Critical Care Procedures: Live Tissue vs. Synthetic Models*. Poster presentation at CHEST Annual Meeting 2018, San Antonio, Tex.