



USDA-APHIS-Animal Care



ANIMAL WELFARE COMPLAINT			
Complaint No. AC19-067	Date Entered: 1-Feb-19	Processed By: SPR	
Referred To: Carlson/Miller		Reply Due: 5-Mar-19	
Facility or Person Complaint Filed Against			
Name: Penn State University		Customer No.: 306	License No.: 23-R-0021
Address: 500 University Dr		Email Address:	
City: Hershey	State: PA	Phone No.: 17033	
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.: (b) (6), (b) (7)(C), (b) (7)(D)	
How was the Complaint received? Email			
Details of Complaint: SEE ATTACHED			
Results:			
Application Kit Provided: Yes: ☐ No: ☒			
Inspector:			Date:
Reviewed By:			Date:

From: [Gibbens Robert - APHIS](#)
To: [ACEASTI](#); [AC West](#); [Neafsey Michael F - APHIS](#); [Miller Dana - APHIS](#)
Subject: FW: APHIS Complaint v. Penn State Milton S. Hershey Medical Center
Date: Tuesday, December 18, 2018 3:23:22 PM
Attachments: [pastedImage.png](#)
[2018-12-19 \(Penn State APHIS Complaint\).pdf](#)
[EM residency survey \(2018-12-12\).pdf](#)
[EM training references \(summaries\).pdf](#)
[Key Simulation Devices for EM Training 2018-10-02.pdf](#)
[image001.png](#)

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: Tuesday, December 18, 2018 2:06 PM
To: Gibbens, Robert - APHIS <Robert.M.Gibbens@aphis.usda.gov>
Subject: APHIS Complaint v. Penn State Milton S. Hershey Medical Center
December 18, 2018

Dear Dr. Gibbens:

Attached and pasted below is a complaint from the (b) (6), (b) (7)(C), (b) (7)(D) regarding the use of live pigs for emergency medicine procedural training at Penn State Milton S. Hershey Medical Center. Our complaint describes what we believe to be violations of specific elements of the federal Animal Welfare Act.

Also attached are three other pdf documents as supporting evidence: (1) Our emergency medicine curriculum survey showing that 94 percent of surveyed programs do not use animals; (2) Emergency medicine training reference summaries documenting the equivalence or superiority of simulation compared to animal use; (3) Key simulation devices for replacing animal use in emergency procedure training.

We request that USDA APHIS inspect the records and facilities at Penn State Milton S. Hershey Medical Center and find the program in violation of the Animal Welfare Act. We further request that the program be required to come into compliance with the AWA by replacing animal use for emergency medicine procedure training.

Sincerely,



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

Dec. 19, 2018
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 Penn State Milton S. Hershey Medical Center

Dear Dr. Gibbens:

(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 Penn State Milton S. Hershey Medical Center. The medical center uses pigs to teach procedures to emergency medicine residents, despite the widespread availability and implementation of nonanimal training methods that are both educationally and ethically superior.

It was confirmed by telephone on Sept. 18, 2018, that emergency medicine residents participate in procedure labs using pigs. Since Penn State Hershey Medical Center is a “state-related” institution and not a public 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)

The medical center’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 (248 of 264)—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, local emergency medicine residency programs at UPMC (Pittsburgh and Erie campuses), the University of Pennsylvania, and Drexel University use only human-relevant training methods.

Under the Animal Welfare Act, Penn State 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). Penn State’s Hershey Medical Center campus is currently registered with the U.S. Department of Agriculture under cert. no. 23-R-0021 (the medical center was previously registered under cert. no 23-R-0161).

It is noteworthy that during a routine inspection conducted on June 13, 2017, USDA cited Penn State Hershey Medical Center for violations of the Animal Welfare Act. On March 9, 2017, an adult sheep underwent cardiac bypass surgery under a protocol that was not approved for survival surgeries, and thus did not have IACUC-approved requirements for surgical aftercare in place. The sheep was euthanized on March 13 due to complications. Following the death of the animal, lab personnel attempted to transfer the sheep to another protocol which included approved cardiac bypass surgery and recovery procedures – clearly demonstrating the staff’s intention to circumvent federal law.

Other USDA inspection reports for the medical center include citations for violations related to personnel qualifications, the IACUC, sanitation, and failure to provide environmental enhancement to promote psychological well-being of animals. In addition, the Hershey Medical Center was issued an official warning for violation of federal regulations for an animal’s death on Dec. 24, 2010, caused by the improper training of animal care staff.

Penn State Hershey Medical Center has clearly demonstrated a pattern of violating the Animal Welfare Act.

Considering that pattern, the (b) (6), (b) (7)(C), (b) (7)(D) believes that inadequate oversight by the university'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 14 years, animal use among surveyed emergency medicine residency programs has declined from 86 percent (Custalow 2004, published survey) to 6 percent (16 of 264 responding 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* in 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 majority 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 Penn State's emergency medicine procedural training.

In addition, the university has a state-of-the-art facility—the Penn State Hershey Clinical Simulation Center—which offers a range of high-fidelity mannequins and partial task trainers that provide the simulation capabilities to replace the use of animals in the emergency medicine residency.

2. The Use of Pigs 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 pigs is not “unavoidable.”

3. The Penn State 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.”

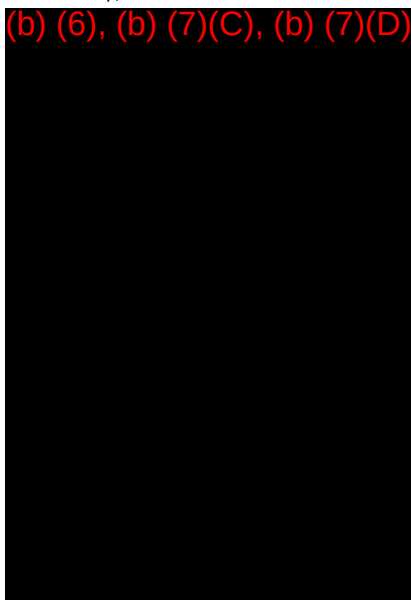
We believe that these requirements were not met by Penn State's IACUC because the animal use protocol was approved despite the violations described in items 1 and 2 above. Thus, the (b) (6), (b) (7)(C), (b) (7)(D) alleges inadequate institutional oversight by Penn State's IACUC.

Accordingly, the (b) (6), (b) (7)(C), (b) (7)(D) requests that APHIS investigate this matter to find Penn State Hershey Medical Center 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)



Addendums

I. Animal Use in Allopathic and Osteopathic Emergency Medicine Residency Programs in the United States: An Ongoing Survey

II. Emergency Medicine Training References: Research and Reviews

III. Simulation for Emergency Medicine Residency Training: A Sampling of Key Devices

[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.

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

Dec. 19, 2018

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 Penn State Milton S. Hershey Medical Center

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 Penn State Milton S. Hershey Medical Center. The medical center uses pigs to teach procedures to emergency medicine residents, despite the widespread availability and implementation of nonanimal training methods that are both educationally and ethically superior.

It was confirmed by telephone on Sept. 18, 2018, that emergency medicine residents participate in procedure labs using pigs. Since Penn State Hershey Medical Center is a “state-related” institution and not a public 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)

The medical center’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 (248 of 264)—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, local

emergency medicine residency programs at UPMC (Pittsburgh and Erie campuses), the University of Pennsylvania, and Drexel University use only human-relevant training methods.

Under the Animal Welfare Act, Penn State 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). Penn State’s Hershey Medical Center campus is currently registered with the U.S. Department of Agriculture under cert. no. 23-R-0021 (the medical center was previously registered under cert. no 23-R-0161).

It is noteworthy that during a routine inspection conducted on June 13, 2017, USDA cited Penn State Hershey Medical Center for violations of the Animal Welfare Act. On March 9, 2017, an adult sheep underwent cardiac bypass surgery under a protocol that was not approved for survival surgeries, and thus did not have IACUC-approved requirements for surgical aftercare in place. The sheep was euthanized on March 13 due to complications. Following the death of the animal, lab personnel attempted to transfer the sheep to another protocol which included approved cardiac bypass surgery and recovery procedures – clearly demonstrating the staff’s intention to circumvent federal law.

Other USDA inspection reports for the medical center include citations for violations related to personnel qualifications, the IACUC, sanitation, and failure to provide environmental enhancement to promote psychological well-being of animals. In addition, the Hershey Medical Center was issued an official warning for violation of federal regulations for an animal’s death on Dec. 24, 2010, caused by the improper training of animal care staff.

Penn State Hershey Medical Center has clearly demonstrated a pattern of violating the Animal Welfare Act. Considering that pattern, the (b) (6), (b) (7)(C), (b) (7)(D) believes that inadequate oversight by the university’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 14 years, animal use among surveyed emergency medicine residency programs has declined from 86 percent (Custalow 2004, published survey) to 6 percent (16 of 264 responding 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* in 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 majority 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 Penn State’s emergency medicine procedural training.

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.

In addition, the university has a state-of-the-art facility—the Penn State Hershey Clinical Simulation Center—which offers a range of high-fidelity mannequins and partial task trainers that provide the simulation capabilities to replace the use of animals in the emergency medicine residency.

2. The Use of Pigs 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 pigs is not “unavoidable.”

3. The Penn State 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.”

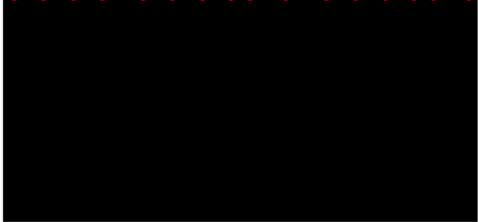
We believe that these requirements were not met by Penn State’s IACUC because the animal use protocol was approved despite the violations described in items 1 and 2 above. Thus, the (b) (6), (b) (7)(C), (b) (7)(D) alleges inadequate institutional oversight by Penn State’s IACUC.

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

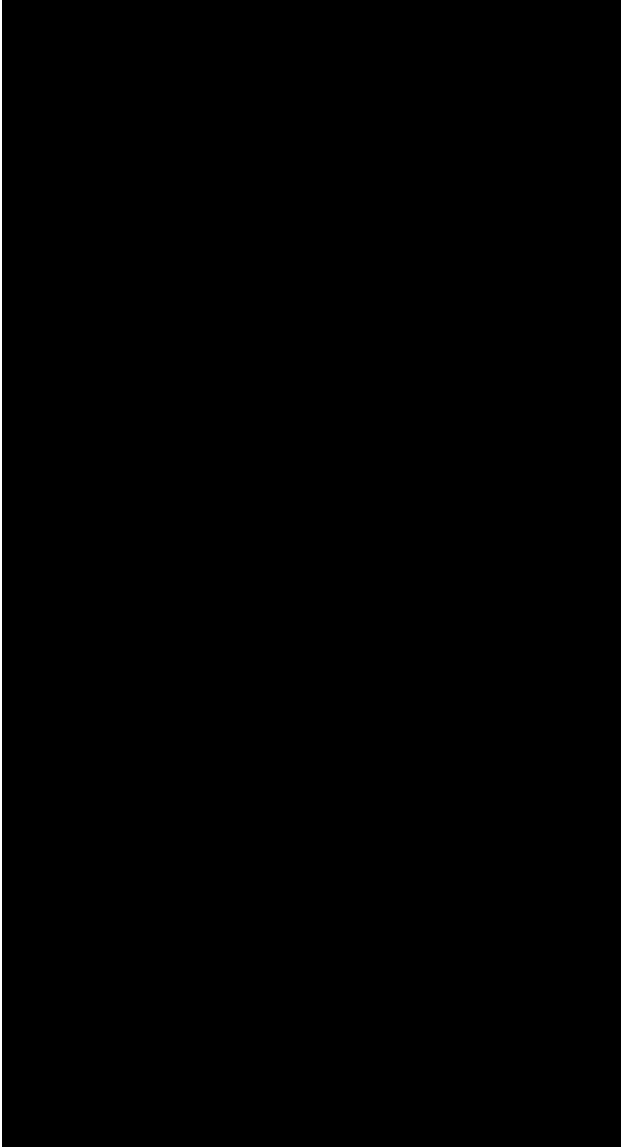
Thank you for your attention.

Sincerely,

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

A large black rectangular redaction box covers the signature and any accompanying text in the signature block.

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



Addendums

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