Jan. 28, 2021

Robert Gibbens, DVM
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USDA/APHIS/Animal Care
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Building B, Mailstop 3W11
Fort Collins, CO 80526-8117

Submitted by email (Robert.M.Gibbens@aphis.usda.gov)

Re: Use of Live Animals for General Surgery Residency Training at the University of Arizona Tucson

Dear Dr. Gibbens:

The Physicians Committee for Responsible Medicine requests that the Animal and Plant Health Inspection Service (APHIS) investigate the use of live animals for training at the University of Arizona College of Medicine – Tucson (UA Tucson), which is using animals to teach procedures to general surgery residents. This occurs despite the widespread use of educationally superior nonanimal training methods.

According to documents obtained by the Physicians Committee under the Arizona Public Records Law, the animal use protocol for the “Arizona Center for Endoscopic Surgery (ACES) Residency Training Course” is approved to use up to 183 pigs over three years. Some of the procedures performed under this protocol include:

- Laparoscopic Cholecystectomy (incisions are made to insert surgical tools and a lighted camera in order to remove the gallbladder)
- Laparoscopic Nephrectomy (incisions are made to insert surgical tools and a lighted camera in order to remove all or part of a kidney)
- Laparoscopic Nissen Fundoplication (incisions are made to insert surgical tools and a lighted camera, and a portion of the stomach is wrapped around the esophagus)
- Laparoscopic Splenectomy (incisions are made in the abdomen to insert surgical tools and a lighted camera in order to remove the spleen)

UA Tucson’s animal use is at odds with the current standards of practice in general surgery residency training in the United States. According to an ongoing Physicians Committee survey, 76% of U.S. general surgery residencies (198 of 259) exclusively use nonanimal methods (see Addendum I). Other surgery residency programs in the state—including Mayo Clinic Phoenix, Midwestern University at Mountain Vista Medical Center, and UA’s other general surgery
residency program at the Phoenix campus—use only human-relevant nonanimal methods for training general surgery residents.

Under the Animal Welfare Act, UA Tucson meets the statutory definition of a “research facility” and is therefore required to comply with the statute’s regulations and standards. As part of this required compliance, any use of live animals for research, testing, or training must be approved by UA Tucson’s IACUC. UA Tucson is currently registered with the U.S. Department of Agriculture (USDA) under certification number 86-R-0003.

The Physicians Committee believes that inadequate oversight by UA Tucson’s IACUC is responsible for the improper approval and ongoing use of live animals in its general surgery residency program. The specific regulatory violations are the following:

1. **UA Tucson’s Justification of Animal Use Is Insufficient Because Alternatives Exist**

Section 2143 of the Animal Welfare Act and C.F.R. 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.

We believe that the PI did not meet this requirement because justification of animal use for general surgery residency training is not possible in view of the validation and widespread implementation of numerous nonanimal training methods. Having not provided objective evidence to support animal use in view of these alternatives, this requirement of the Animal Welfare Act was not met.

A proper alternatives search would have revealed nonanimal methods for the training of surgery residents and an abundance of peer-reviewed literature demonstrating the equivalence or superiority of simulation-based surgery training compared to animal use. Over the last three decades, surgical simulation has evolved with advances in technology and an imperative to replace the use of animals in surgery training courses. All surgery skills, including both open and laparoscopic procedures, can be taught using human-based methods, such as human-patient simulators, laparoscopic simulators, virtual reality simulators, human cadavers, and partial task trainers.

A study funded by the U.S. Army compared the physiological stress response in trainees using medical simulators versus live animals. The study, which was presented on Oct. 10, 2018, at the annual meeting of the American College of Chest Physicians 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.”

There are many validated and widely implemented nonanimal simulation methods available to train general surgery residents, including the LAP Mentor by 3D Systems (formerly Simbionix),

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which UA Tucson already owns. LAP Mentor is a laparoscopic surgical simulator with advanced haptics and features a library of training modules, including basic and advanced suturing, incisional and inguinal hernia, nephrectomy, cholecystectomy, sigmoidectomy, Nissen fundoplication, gastric bypass, and lobectomy. Surgical Science’s LapSim is a virtual reality laparoscopic simulator that can be used to train cholecystectomy, nephrectomy, suturing and anastomosis, appendectomy, hysterectomy, inguinal hernia repair, lobectomy, and bariatric procedures.

Maximum Fidelity Surgical Simulations’ EnvivoPC uses state-of-the-art technology—including simulated blood and a pump—to create a perfused cadaver that mimics heart function and circulation while allowing for hands-on training in procedures involving active bleeding. EnvivoPC can be used to perform a variety of surgical procedures, including cholecystectomy, nephrectomy, splenectomy, colectomy, bowel resection and anastomosis, liver resection, and ventral and para-esophageal hernia repair.

Another long-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 chest tube placement, tracheostomy, diagnostic peritoneal lavage, cricothyroidotomy, pericardiocentesis, needle decompression, pneumothorax drainage, tracheostomy, and intravenous cutdown. Simulab also offers a Surgical Abdomen for TraumaMan (or as a stand-alone trainer), that features simulated pumping blood and can be used for both open and laparoscopic procedures, including repair of a nicked or lacerated aorta, renal artery, and kidney, cholecystectomy, and options to build individualized training modules. The TraumaMan System is endorsed by the American College of Surgeons for trauma training and is used by many Advanced Trauma Life Support (ATLS) programs.

Addendum II presents a sampling of key training devices available to replace animal use in UA Tucson’s general surgery residency training.

In addition, the university already has a 30,000 square foot state-of-the-art facility—the Arizona Simulation Technology and Education Center—which offers a range of high-fidelity patient mannequins, virtual reality trainers, and procedural task trainers that could provide the simulation capabilities to replace the use of animals in the general surgery residency.

2. The Use of Animals for General Surgery Residency 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 76% of surveyed U.S. general surgery residency programs do not use live animals. This clearly demonstrates that such use of live animals is not “unavoidable.”
3. UA Tucson’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 C.F.R Title 9, Section 2.31(d).

We believe that these requirements were not met by UA Tucson’s IACUC because the animal use protocol was approved despite the violations described in items 1 and 2 above. Thus, the Physicians Committee alleges inadequate institutional oversight by UA Tucson’s IACUC.

Accordingly, the Physicians Committee requests that APHIS investigate this matter to find UA Tucson and its IACUC in violation of the Animal Welfare Act and its implementing regulations, as detailed above, and to order correction and appropriate penalties.

Thank you for your attention.

Sincerely,

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Addendums
I. Animal Use in General Surgery Residency Programs in the United States: An Ongoing Survey
II. Simulation for General Surgery Residency Training: A Sampling of Key Devices