August 19, 2024

Brent C. Morse, D.V.M. Director Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health

Via e-mail: MorseB@mail.nih.gov

Dear Dr. Morse:

I'm writing on behalf of People for the Ethical Treatment of Animals— PETA entities have more than 9 million members and supporters globally to request that your office investigate possible noncompliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) and the *Guide for the Care and Use of Laboratory Animals* (the Guide) related to serious safety concerns with the use of live animals in experiments at the Louisiana State University Health Sciences Center (LSU; Animal Welfare Assurance ID D16-00058).

According to a July 9, 2024, U.S. Department of Agriculture (USDA) <u>inspection report</u> for LSU, a non-survival Cesarean-section (C-section) was performed on a pig on February 23, 2024. During this surgery, "practices and procedures" were performed that weren't approved by the Institutional Animal Care and Use Committee (IACUC). The IACUC-approved protocol required the "use of personal protective equipment (PPE) including head cover, surgical mask, sterile gown, and sterile gloves." However, multiple participants in the surgery, including the principal investigator (PI), didn't wear proper PPE.

The IACUC-approved protocol also detailed that the C-section carried "an expectation of higher mortality among preterm pigs as compared with preterm human infants." Therefore, piglets who experienced respiratory distress or met an IACUC-approved criteria for euthanasia "would not be intubated for resuscitation." However, laboratory "personnel made efforts to intubate and resuscitate the piglets[,] but the animals were too small and the ventilation equipment was too big to revive the piglets."

In regard to these multiple forms of lack of adherence to the IACUCapproved protocol, the inspection report states, "It is important that animal usage occurs exactly as approved by the IACUC to ensure required animal welfare standards are appropriately met with current veterinary practices and institutional policies."

Additionally, the PI allowed forty-two students to participate in the Csection, which also "involved recovery and nursing of preterm piglets." The students were required to go through an "approval and training process from PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

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the Safety Office and IACUC (e.g. completion of applicable online training modules and submission of Occupational Health evaluations)," but the students didn't complete this process prior to the surgery date. The inspection report notes, "It is critical that personnel be qualified and trained prior to performing animal work to ensure both personnel safety and animal welfare."

Furthermore, during the C-section, the PI allowed their dog "to be walking freely and unsupervised in the main hallway connecting to the surgical suite and neonatal intensive care unit areas." The dog also freely accompanied the PI and the USDA veterinary medical officer, walking through the surgery suite as well as other areas intended to nurse both premature and neonatal piglets after delivery via experimental Caesarian-section." The inspection report summarizes:

Aseptic conditions are not being maintained due to presence of a pet dog in the major operative surgical areas of the SRF facility. This poses health risks to the sows and their preterm piglets; has the potential to introduce stressors such as dander, allergens, and biological agents to highly susceptible immune suppressed piglets; and could ultimately compromise research integrity.

# The issues raised in the USDA's inspection report for LSU also indicate noncompliance with PHS Policy and the Guide.

# Failure of program oversight and staff training

The Guide instructs that an institution's animal care and use program must include adequate policies, procedures, and practices "to achieve the humane care and use of animals in the laboratory and throughout the institution" (p. 6). Additionally, the institution must maintain an environment in which the IACUC can "function successfully to carry out its responsibilities" and the institution is responsible for ensuring that "IACUC members are provided with training opportunities to understand their work and role" (pp. 6 and 17). Furthermore, the IACUC is responsible for "assessment and oversight" of the institution and should have "sufficient authority and resources (e.g., staff, training, computers, and related equipment) to fulfill this responsibility" (pp. 14–15).

In addition to establishing this responsibility of the IACUC, the Guide addresses the importance of proper training for staff involved in animal care and surgeries. It states, "Personnel caring for animals should be appropriately trained ... and the institution should provide for formal and/or on-the-job training to facilitate effective implementation of the Program and the humane care and use of animals. Staff should receive training and/or have the experience to complete the tasks for which they are responsible" (p. 16). Furthermore, "[t]he institution should provide appropriate education and training to members of research teams—including principal investigators, study directors, research technicians, postdoctoral fellows, students, and visiting scientists—to ensure that they have the necessary knowledge and expertise for the specific animal procedures proposed and the species used" (pp. 16–17).

The IACUC also has the responsibility—under federal law, regulations, and policies—to continually monitor the use and care of animals (p. 33). Post-approval monitoring includes "observation of animals by animal care, veterinary, and IACUC staff and members" (p. 33).

The failures of the LSU IACUC to ensure and monitor that staff followed approved protocols which led to required PPE not being worn and too-large ventilation equipment being pushed down the throats of piglets in distress—illustrate a complete breakdown in the institution's animal care and use program. The actions of LSU personnel not only show a disregard for following protocol, but seemingly reflect an utter lack of concern for the safety and welfare of both human and non-human animals.

Additionally, a PI allowing forty-two untrained students to interact with animals during a procedure that included newborns in distress and letting their dog walk around a surgery suite suggests a serious lack of training and experience among personnel. LSU's program has failed to train staff in the most basic of surgical guidelines to ensure safety.

# Failure to follow proper surgical procedures and aseptic technique

The Guide states, "Successful surgical outcomes require appropriate attention to presurgical planning, personnel training, anesthesia, aseptic and surgical technique, assessment of animal well-being, appropriate use of analgesics, and animal physiologic status during all phases of a protocol involving surgery and postoperative care" (p. 115). Additionally, "[s]urgical outcomes should be continually and thoroughly assessed to ensure that appropriate procedures are followed and timely corrective changes are instituted" (p. 115).

Additionally, "[r]esearchers conducting surgical procedures must have appropriate training to ensure that good surgical technique is practiced," including "appropriate use of instruments" and asepsis (p. 115). "Unless an exception is specifically justified as an essential component of the research protocol and approved by the IACUC, aseptic surgery should be conducted in dedicated facilities or spaces" (p.116). The Guide explains that "[a]septic technique is used to reduce microbial contamination to the lowest possible practical level" and aseptic technique includes "preparation of the surgeon, such as the provision of appropriate surgical attire, face masks, and sterile surgical gloves" (i.e., PPE) and "sterilization of instruments, supplies" (p. 118). The Guide cautions that "inadequate or improper technique may lead to subclinical infections that can cause adverse physiologic and behavioral responses...affecting surgical success, animal well-being, and research results" (p. 118).

During the C-section at LSU, proper attention was not given to presurgical planning, personnel training, aseptic and surgical technique, or assessment of animal well-being given that personnel did not wear proper PPE, personnel attempted to intubate piglets with equipment that was too large, students weren't trained, and a dog was permitted in surgical areas.

**In conclusion**, we urge you to investigate the concerns summarized in this letter and to take swift and decisive action against LSU. In FY 2023 alone, the National Institutes of Health (NIH) awarded LSU Health Sciences Center nearly \$26 million. Such funding should be able to ensure that a program functions properly, but LSU has proved that it can't meet even basic

animal welfare requirements or safety considerations, regardless of what resources it has and so LSU should no longer receive NIH funding, and its Animal Welfare Assurance should be revoked.

Thank you for your attention to this important matter. Please do not hesitate to contact me with any questions at <u>AmandaE@peta.org</u>.

Sincerely,

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