RUTGERS

IACUC Office
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p 732-235-9081

November 22, 2019

Brent Morse, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Re: Animal Welfare Assurance Number D16-00098 (A3158-01)

Dear Dr. Morse,

Rutgers, The State University of New Jersey, hereby makes the final report for the following incident, reported to OLAW via telephone on November 20, 2019. On July 22, 2019, two pigs were implanted with a stent from a different manufacturer than stated in the approved protocol. One pig developed fever, vomiting, and anorexia two days following the procedure. This pig was treated and recovered. The second pig developed abdominal pain and fever the day following the procedure. This pig did not respond to treatment and was euthanized. Necropsy showed that the bowel adjacent to where stent was placed may have been damaged during surgery, resulting in perforation of bowel. Further investigation indicated that the power device used to create the entrance into the small bowel did not cut through bowel wall as effectively as expected so that the operator needed to use more pressure than expected which may have led to the damage to the bowel adjacent to where stent was placed.

The following actions were taken in response to this incident:

- The PI was counseled by the Chair of the IACUC and Comparative Medicine Resources (CMR) veterinary staff.
- The laboratory members completed online training.
- The stent manufacturer was made aware of the potential issue and the lab will not use it again until it is upgraded and tested in ex-vivo tissue.
- An amendment to add the use of an additional stent by a different manufacturer was submitted to the IACUC protocol and approved.
- Future surgeries by the laboratory staff must be done under CMR veterinary team supervision.
- The lab was required to develop and submit a checklist detailing the list of procedures to be performed for each surgery. This checklist must be signed off by the appropriate staff member prior to conducting future surgeries to ensure they follow the approved protocol.
- At a convened meeting on August 13, 2019, the IACUC reviewed and discussed this incident and unanimously voted to report this matter to OLAW. The IACUC also voted to accept the above noted corrective actions.

Please note that this study was not supported by NIH funds.

Please contact me with any questions.

Sincerely,

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S. David Kimball, Ph.D.
Institutional Official
Senior Vice President, Research & Economic Development
Vice President, Innovation & Research Commercialization

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Obtained by Rise for Animals.
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