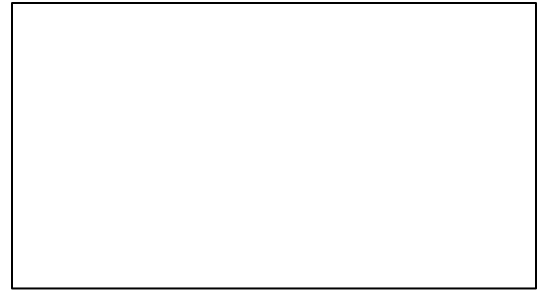




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Clinical Research Project Client Consent Form

Study Title: Assessing Postoperative Pain in Pigs After Celiotomy or Laparoscopic Spay

Principal Investigator: Jamie L. Stewart
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One of the missions of the Virginia-Maryland College of Veterinary Medicine is to create, disseminate and apply medical knowledge through discovery, learning, and engagement. You are invited to participate in this mission by enrolling your animal in a clinical research study. Your participation is voluntary, and you may withdraw your animal from the study at any time by notifying the Principal Investigator. There is no penalty if you choose not to participate.

Study Purpose:

In the United States, miniature pigs are increasing in popularity amongst pet owners. Spaying of female pigs is typically recommended by veterinarians to decrease the risk of cancer formation and reduce aggressive behaviors associated with the reproductive cycle. Traditional spays require invasive abdominal surgery to remove both the uterus and ovaries. However, in dogs and cats, removal of just the ovaries has been demonstrated to adequately reduce both cancer risks and behavioral issues. Ovary removal can be performed laparoscopically, which decreases the risks of post-surgical complications associated with abdominal surgery. The outcomes of this technique have been studied extensively in dogs and cats, but there is minimal data available in pet pigs. Therefore, this study aims to demonstrate that laparoscopic ovary removal will have less complications and improve recovery in pet pigs compared to the traditional abdominal surgery technique.

Study Design/Procedures:

This project will take place while the pig is in hospital for its routine spay procedure (2 days). Each pig will be randomly assigned to undergo either a routine surgical ovariectomy (where both ovaries and uterus are removed) or a laparoscopic ovariectomy (where only the ovaries are removed). While in hospital, the pet will undergo routine standard-of-care in regards to anesthesia, surgery, and post-surgical monitoring. Currently, the laparoscopic procedure is ~\$500 more expensive to perform in our hospital due to the sophisticated equipment required. The grant will cover the additional \$500 for pigs randomly selected to undergo the laparoscopic procedure, such that the price will be equal to our standard surgical procedure. In addition to the standard monitoring procedures, your pig will receive additional monitoring that includes assessing stress parameters via blood sampling and behavioral scoring at no extra cost to owners. This increased monitoring will benefit the animals by allowing for earlier and better pain management or other post-operative interventions if needed.

If at any time you are uncomfortable with involvement in this project, you can request to no longer be enrolled. Un-enrolling your pig in this project will disqualify you from receiving a stipend towards your veterinary bill (for those enrolled in the laparoscopic procedure) and you will be required to pay the full price for the procedure and any extra monitoring that was already performed.

Owners will be contacted via email and/or over the phone to complete surveys at 1 week, 1 month, 6 months, and 1 year post-operatively. Participation in these surveys are optional, but the input generated will be extremely useful, as we are looking to assess the pet's recovery at home and long-term satisfaction from the clients. We will automatically send a short survey every year, as we are hoping to assess the long-term outcomes of removing ovaries only versus the ovaries and uterus. If at any time, you wish to not receive these surveys, you may contact us and we will remove you from list.

Risks and Benefits:

Spaying pet pigs is a recommended procedure due to the long-term benefits that include improved behavior and decreased likelihood for the development of uterine tumors. We hope to show that performing a laparoscopic ovariectomy will result in the same benefits as the traditional surgical ovariectomy, but will allow pigs to recover more easily from the operation and improve owner satisfaction. Both procedures present the same risks as any abdominal surgery,

which include post-operative pain, hemorrhage, infection, herniation, or death. These complications are rare. Enrollment in the study will not increase the risk of complications, but rather may allow us to identify any post-operative complications sooner due to increased monitoring.

Study Costs and Compensation:

Financial compensation will be provided to owners whose pigs are selected to undergo laparoscopic ovariectomy. This \$500 compensation will adjust the surgery price so that it is comparable to our routine surgery procedure (\$600-800 for pigs 150 lb. or less).

The grant will also cover the cost of additional blood and behavioral monitoring that will be performed post-operatively.

The grant will not cover the hospital stay, anesthesia/intra-operative monitoring fees, or surgery time/supplies/drugs that would normally be used in these procedures.

Confidentiality:

The data collected in the course of this study is confidential. In any publication or presentation of the study data, we will not include information that would make it possible to identify a research participant. Research records will be kept in a secure location; only researchers will have access to the records. The Theriogenology Foundation will not have access to the data, but outcomes will be reported to the foundation and presented at the Theriogenology meeting.

Statement of Consent:

In giving my consent by signing this form, I acknowledge that I have been informed of the purpose and nature of this study and its associated procedures, as well as any possible side effects.

I have read and understood the above information. I have been given the opportunity to ask questions and receive answers, and I consent to participate in the study. I further certify that I am the owner (or duly authorized agent of the owner) of _____ .
(Animal's name)

Owner or Agent Signature: _____ Date: _____

Owner or Agent Printed Name: _____

Attending Clinician Signature: _____ Date: _____

Attending Clinician Printed Name: _____

Please don't hesitate to contact us if you have any questions or concerns about this study.

The research and procedures have been reviewed and approved by the Virginia Tech Institutional Animal Care and Use Committee and the Virginia-Maryland College of Veterinary Medicine Clinical Research Review Committee.

If you have any questions or concerns regarding the study and would like to talk to someone other than the researchers, please contact:

Hospital Director,
Veterinary Teaching Hospital
Address: 245 Duck Pond Dr.,
Blacksburg, Virginia 24061-0443
Phone: 540.231.4621

You will be given a copy of this form to keep for your records.