

Virginia Polytechnic Institute and State University Veterinary Teaching Hospital Address: 245 Duck Pond Dr., Blacksburg, Virginia 24061-0443 Phone: 540-231-4621 | Fax: 540-231-9354



# Clinical Research Project Client Consent Form

Study Title: Identification of a genetic predisposition for Equine Protozoal Myeloencephalitis (EPM) susceptibility and associated gene dysregulation in clinically affected horses Principal Investigator: Dr. Sharon Witonsky 540-231-9042; switonsk@vt.edu

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 entirely 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:**

By collecting samples from normal horses and those affected by Equine Protozoal Myeloencephalitis (EPM), we hope to understand the genetic predisposition for the disease. This could lead to earlier risk management, diagnosis, treatment, and potentially immune modulators which could improve disease outcomes.

#### Study Design/Procedures:

EPM is a devastating equine neurological disease. From this study, in Aim 1, we will determine whether chronically affected EPM horses with progressive disease have a difference in major histocompatibility complex (equine leukocyte antigen) difference vs. control horses. We will also determine if EPM affected horses, which are not responding poorly, have differences in ELA vs. chronically affected poor doing EPM horses and vs. control horses. A blood sample or 50 hairs with bulbs will be collected for Aim 1. For Aim 2, we will put your horse in one of these groups (EPM-affected or normal), we will perform a neurologic exam and collect blood. After your horse is euthanized, we will collect cerebrospinal fluid (CSF) and samples for histopathology to assess the immune response and identity infection by *Sarcocystis neurona*.

# **Risks and Benefits:**

EPM can be a devastating disease with long term permanent deficits to horses that develop disease. In some rare cases, affected horses may recover without treatment. However, many horses that develop disease may have permanent neurologic changes, and may be limited in what they can do. Many affected horses, if they continue to get worse, and treatment is not chosen, can develop progressive disease to the point that they may need to be euthanized.

# Study Costs and Compensation:

Microsatellite analysis for ELA testing will be performed on blood samples. Euthanasia, testing for EPM (if needed), and necropsy fees will be included for select horses.

# **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 locked file; only researchers will have access to the records.

#### 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:	
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Attending Clinician Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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 (IACUC 15-070) and the Virginia-Maryland College of Veterinary Medicine Veterinary Teaching Hospital Board.

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

Dr. Terry Swecker Hospital Director, Veterinary Teaching Hospital Virginia-Maryland College of Veterinary Medicine 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.