Appendix 5 OWNER CONSENT RECORD

Investigational Veterinary Product (IVP) Information			
Study Name:	Field Effectiveness of Orogin® for the treatment of EPM	Study site #:	
IVP:	Orogin® (136 mg decoquinate/275 mg levamisole HCl)	Control:	Protazil®
Formulation:	Tablet		Pellet
Treatment Claim:	For the treatment of Equine Protozoal Myeloencephalitis caused by *Sarcocystis neurona*		

Study Information			
Animal ID #:			

Owner Consent (Please sign prior to first treatment)

Original copy retained by Field Investigator - copy provided to Owner

I, the owner, understand that this study tests an *investigational veterinary product* (IVP) for the treatment of Equine Myeloencephalitis (EPM) caused by *Sarcocystis neurona* against Protazil® (CP) in a blinded study. The purpose of thi obtaining effectiveness data for Food and Drug Administration's licensing requirements. Horses will be dosed daily fo medication that includes CP and placebo tablet (PT) or IVP and placebo pellet (PP). The animal will receive CP and P during the study. The above named IVP has not been approved for sale in the United States for the claim being studi been subjected to testing for efficacy and safety. Although it is not expected, there is a risk of adverse reactions and potential harm to a nursing foal or gestating fetus; hence, I am aware that a breeding animal (stallion or pregnant m participate in the study. If any of the following adverse events such as allergic reaction, salivation, increased sensitivi depression, diarrhea, colic, muscle tremors, ataxia (unsteady and uncoordinated movement), seizures, or collapse oc study I will contact the Field Investigator. The safe use of Protazil® and IVP in horses used for breeding purposes, du in lactating mares, or with concomitant therapies has not been evaluated.

I understand that I am responsible to administer medication, tablet (10 days) and concurrently administer a feed pelle days and collect information regarding the animal's health by completing the Daily Client Observation form and return Forms. I understand that there will be a follow-up phone call one week after the end of the study. I have made a fully regarding other diagnostic considerations and the use of the IVP creates an obligation not to sell this animal for food fo treatment. I have the right to withdraw from the study at any time and for any reason without penalty.

***Owner Name:**		**Phone #:**	
Owner Address:		**Fax #:**	
City, State, Zip:		**Email:**	
Owner Signature:		**Date:**	

***Note:** In the absence of the owner, an authorized agent is permitted to give informed consent provided the above information has been discuss and the owner has given verbal consent to the authorized agent.