MR#_____ Owner Name: _____
Patient Name: _____

INFORMED CONSENT FORM
A Low-Cost Treatment for Cranial Cruciate Ligament Disease

Principle Investigator: Western University Health Sciences: Drs Dominique Griffon, DVM, MS, PhD, Dip ACVS, Dip ECVS

Purpose of Study: Cranial cruciate ligament deficiency (CCLD) is a common problem in the stifle (knee) of dogs, causing pain and lameness due to chronic tears of a ligament crossing the knee. The purpose of this study is to evaluate a cost-effective, simple, and minimally invasive surgery to treat this disease. The new technique (percutaneous lateral fibular suture) is a technique that resembles the suture repair routinely performed by veterinarians to treat CCLD in dogs, where a suture is placed around the knee to stabilize it. However, the new technique eliminates the need for long incisions in the tissues and does not enter into the knee. We believe that this technique will be faster, cost less, and allow dogs to use their limbs faster than the traditional suture repair routinely performed to treat dogs with CCLD.

Eligibility: Adult healthy dogs with lameness on one rear limb attributed to cranial cruciate ligament disease (CCLD). Dogs of all breeds may be eligible if they weigh less than 60kg (80 lbs).

Procedures:

- ☑ *Clinical examinations* before, after (24-48 hours) and 2, 6 and 12 weeks after surgery. Clinical examination will be used to confirm the presence of CCLD in one limb. **Dogs with clinical signs of concurrent disease in the stifle (such as meniscal disease) will be excluded.**
- ☑ *Surgery* of the affected limb either by **1-Traditional lateral fabella suture repair or 2-New lateral fabella suture repair-** The procedure will be randomly assigned.
- ☑ *Owners questionnaires*: Owners will complete a standardized questionnaire evaluating function, pain, and quality of life before, 2, 6 and 12 weeks after surgery
- ☑ *Radiographs of the stifle* will be taken before, immediately after, 6 and 12 weeks after surgery.
- ☑ *Thermal imaging:* Digital pictures of your pet will be taken with a special camera that detects differences in temperature of the skin. This test will be done to quantify inflammation before, after (24-48 hours), 2 and 6 weeks after surgery.
- ☑ *Pressure gait analysis:* Your pet will stand, walk or trot on a treadmill and a mat designed for dogs so we can measure the amount of weight placed on the limb. This assessment will be done in standing position (at all times), at the walk (before and at 2,6, and 12 weeks after surgery) and at the trot (12 weeks after surgery).

Associated Risks: Clinical examinations, radiographs under sedation, and anesthesia are required to treat the disease and will carry the same risks as those performed in dogs treated with CCLD. Potential risks may include hypotension, hypertension, cardiac arrhythmia and in extremely rare cases may result in death. Similarly, the **outcomes and complications associated with the surgeries are the same as those encountered in dogs treated with the LFS**, including postoperative swelling, infection, persistent lameness, suture rupture, and meniscal tear. These complications are unusual, affecting 5-18% dogs. Because the new technique does not enter into the joint, preexisting disease that is not detected on preoperative evaluation may be undiagnosed and cause persistent signs after surgery. The only tests done specifically for the study consist of thermal imaging and gait analysis. No complication is specifically associated with these tests.

Compensation: Owners will be expected to pay $200 toward the cost of treatment of the CCLD, refunded once all follow-up data have been collected. Clinical examinations, surgery, radiographs, thermal imaging, and pressure gait analysis of the hind limbs will therefore be done at no cost to the client. Any other procedures performed that are not directly related to the project will be the responsibility of the client. Clients may be responsible for all or part of the charges accrued to date upon

disqualification/voluntary withdrawal. Owners of dogs excluded after initial evaluation will not be charged for the clinical examination.

I understand that my animal(s) participation in this study is entirely voluntary. Refusal to participate or to continue to participate carries no medical penalty, and I am free to withdraw my animal from this study at any time without medical penalty or prejudice. I understand that my voluntary removal will constitute disqualification from further participation in this study.

I have not withheld information regarding my animal's medical history. I acknowledge that I have read and understand this consent form and all my questions have been answered to my satisfaction.

I have been given a copy of this consent form *if I* have requested a copy.

I am aware that this research has been reviewed and approved by the Institutional Animal Care and Use Committee of the Western University of Health Sciences, Pomona, California.

As a volunteer, I give my informed consent to the Board of Trustees of Western University of Health Sciences and the (… Clinic Center…) to enroll my pet in this study, according to the explanations and conditions presented in this document. I agree to hold harmless the Board of Trustees of Western University of Health Sciences and the (… Clinic Center…), and its officers, employees, agents and assigns from any and all liability, claims and actions that may arise from participation in this study.

_____		_____	
Printed Name: Owner (or authorized agent)		Printed Name: Witness	
_____	_____	_____	_____
Signature of Owner (or authorized agent)	Date	Witness Signature	Date

*IACUC Approval #*_____***Original to Medical Records***