AUBURN UNIVERSITY

COLLEGE OF VETERINARY MEDICINE

DEPARTMENT OF CLINICAL SCIENCES

CLIENT INFORMED CONSENT FORM

Title: The safety and efficacy of a dietary supplement containing cannabidiol (CBD) for treatment of pain in dogs with osteoarthritis

1. **Why is the study being performed?**
   Legalization of industrial hemp has led to dietary supplements containing cannabidiol (CBD) for animals. Among the indications of CBD is chronic pain. Osteoarthritis (OA) is one of the most common causes of chronic pain in dogs. The goal of this study is to determine if a CBD containing dietary supplement is an effective and safe treatment for chronic pain associated with OA in dogs. Dogs will be treated for 6 weeks and response to the treatment will be measured prior to, in the middle and at the end of the 6 week period.

2. **Which animals / patients can participate in the study?**
   Any dog weighing at least 10kg (22 lbs) but less than 40kg (88 lbs), be at least 1 year of age, otherwise healthy, and suffering from pain and lameness associated with previously diagnosed OA involving one or more of the following joints: hip, knee (stifle), ankle (tarsus), shoulder, elbow, or wrist (carpus). The diagnosis of OA must be made based on orthopedic exam, a visually identified lameness in any or all limbs, and radiographs (x-rays) all performed/obtained at Auburn University by the Small Animal Orthopedic Surgery Service. A general examination and baseline blood and urine testing (i.e. CBC/chemistry & urinalysis) will also need to be performed at Auburn University within 4 weeks prior to enrollment to ensure no other health concerns.

3. **Why might my animal NOT be able to participate in the study?**
   Your pet will be excluded from the study if they have evidence of disease other than OA or if they will need to continue medications that might be considered unnecessary or interfering with the effects of CBD. Dogs can be receiving nonsteroidal anti-inflammatory drugs, but only if dosing was unchanged for 4 weeks prior and will remain at the same dose throughout the study. If your pet has received a CBD product in the last 4 weeks, they cannot be included in the study. During eligibility consideration, if your pet is deemed to have excessive pain or lameness warranting immediate new medications and/or surgery, your pet will not be eligible for inclusion in the study. Additionally, your pet will not be allowed to receive any new pain medications or anti-inflammatories during the 6-week study period. If additional pain medication or anti-inflammatory medication is deemed necessary for quality of life during the study, your pet will be withdrawn from the study to allow treatment.

4. What will be happening to my animal if we participate in **the study?**
Once your pet has been enrolled in the study, the level of pain your pet is suffering will be assessed based on orthopedic examination, pressure walkway analysis, a Canine Brief Pain Inventory (CBPI) questionnaire that you will complete, and a health related quality of life survey (HRQS) that you will complete. Then your pet will be randomized to receive one of 4 possible treatments: a dietary supplement fortified with CBD, a dietary supplement without CBD, a pure CBD, or a placebo which looks just like the other dietary supplements. You and the study investigator will not know which treatment your pet is receiving. However, if, in an emergency, the product needs to be revealed, a code will be available through the study investigators at all times. Your animal will need to be treated twice a day, every 12 hrs, at the prescribed dose. A daily record that indicates that both doses were received will be used to confirm dosing. The daily record also will be used to indicate any adverse or side effects that your pet might demonstrate. At three weeks and six weeks, you must bring your pet back so that the blood and urine testing (CBC/chemistry/UA/CBD levels), physical examination, and pressure walkway analysis can be repeated. You will also complete the CBPI questionnaire and HRQS at both visits. At the end of the study, you will be told which treatment your pet was receiving and you will be given, at no additional cost, 4 weeks of the CBD containing dietary supplement.

The dose of the product may be adjusted at the 3 week evaluation if both you and the investigator indicate a need, but no other changes in either the quantity or frequency of administration may be made without approval of the principal investigator. No drugs may be started without the permission of the investigator without risking dismissal from the study.

5. **Are there any benefits from the study for my animal?**
CBD has demonstrated efficacy for control of chronic pain in humans, and in two studies of OA in dogs. As such, your pet may directly benefit from the therapeutic effects of this product. Further, at study end, if your pet completes the study, your pet will receive a month of the CBD containing dietary supplement.

6. Are there any risks or discomforts for my **animal?**
CBD has been demonstrated to be safe in dogs at doses much higher than those your pet will be receiving. Blood work will be collected to confirm safety. The amount of blood being collected at each visit is small (4 teaspoons). Bruising at the site of collection may occur on rare occasions.

7. **Unforeseen adverse events**
In the event of unforeseen adverse events, clinical care will be provided for your pet.

8. **Are there treatment options other than participating in the study?**
This study is evaluating a new therapy for the treatment of pain associated with OA. Other

drugs are available and can be used with NSAIDs.

9. Owner **responsibilities**
Your responsibilities include treating your pet every 12 hrs (or as close to that as possible) for 6 weeks, maintaining a daily record that documents dosing and describes ANY abnormal or out-of-character behavior observed in your pet and making an appointment to have your pet evaluated at week 3 and again at study end (week 6). You will need to complete three CBPI questionnaires and three HRQLS surveys: once before treatment begins, once at 3-weeks into the study, and once at the study end.

10. Participant **dismissal**
You or the principle investigator may withdrawal your pet from the study at any time for any reason. At the time of withdrawal, the cost of all subsequent monitoring, drugs, etc. will be assumed by you, and the study will not provide further financial support.

11. Financial obligations of all **parties**
The study will not pay for the diagnostics necessary to confirm your pet's eligibility to participate in this study. However, once deemed eligible, the study will pay for any scheduled office visit fees, drugs, laboratory tests, the study treatment supplement (**approximate cost of the study that will be covered is ~ $600/participant).** In addition, client will be financially compensated for any adverse complications associated with the study up to a maximum value of $500. The study will not pay for therapies not related to this study.

12. **Access to study information**
At the end of the study, you will be told the product your pet is receiving.

13. Confidentiality
Both you and your pet's participation in this study will remain confidential. Any data presented will not contain either your or your pet's name.

14. Contact persons regarding this **study**
Participants may contact any of these individuals with questions about this study.
Kayla Corriveau, DVM, DACVS-SA. 334-844-4690. kmc0118@auburn.edu
Dawn Boothe, DVM, MS, PhD, DACVIM, DACVCP. 334-844-4751. boothdm@auburn.edu

15. **Hospital review contact person**
Participants with concerns about any research study at the AU College of Veterinary Medicine may also contact:
Bob Kennis. Acting Director, Veterinary Teaching Hospital. College of Veterinary Medicine, Auburn University. (334) 844-4690.
Frank F. "Skip" Bartol, PhD. Associate Dean of Research and Graduate Studies. College of Veterinary

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Medicine; Auburn University. (334) 844-3700.

16. **Owner acknowledgements:**
As legal owner of (or agent for) this animal, I understand and acknowledge the following:
   a. **I am agreeing to participate in a research study at the AU College of Veterinary Medicine.**
   b. **I am free to withdraw my consent and to discontinue participation in the study at any time.**
   c. **The decision for my animal to participate in this study is mine alone and *participation is voluntary.***
   d. **The decision to withdraw from the study or to disregard the recommendations of the veterinarians involved in the study, relieves the investigators of current and future obligations (both medical and financial) to the pet and/or owner covered by this study.**
   e. **Non-study treatment protocols have been discussed and I understand the relative benefits of those treatments.**
   f. **I am responsible for decisions and financial obligations related to treatment(s) sought or required for my animal at AU-VTH or at any other veterinary facility that are NOT specified in this document. This would include treatment for disease progression or for medical complications - related or unrelated to the study.**
   g. **If I withdraw my animal from the study, I may be responsible for medical, diagnostic and treatment costs incurred even if these were originally covered by the study.**
   h. **Any decision to discontinue participation in this study, whether to pursue other therapies or to have my animal euthanized, does not entitle me to any financial reimbursement for costs incurred during participation.**
   i. **I have discussed the procedures / benefits and risks of study participation and had the chance to have my questions about the study answered.**

_____ _____
Owner signature Date

17. **Investigator assurances**
   a. I have explained the study details and answered questions to the best of my ability.
   b. If the animal is a patient in the Auburn University Veterinary Teaching Hospital, I have discussed enrolling the patient into this study with the senior faculty member responsible for this patient's care.

_____ _____
Primary Investigator Date

_____ _____
Witness Date

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This study has been reviewed and approved by the Clinical Research Review Committee of the College of Veterinary Medicine (CRRC) and the Auburn University Institutional Animal Care and Use Committee (IACUC).