

Panacea Life Sciences



INFORMED CONSENT FORM – EQUINE STUDY

This Informed Consent Form (ICF) is for horse owners whom we are invited to participate in research using Cannabidiol (CBD) for the treatment of inflammatory pain and reducing anxiety for horses. The title of our research project is “USE OF CANNABIDIOL (CBD) AS AN EQUINE THERAPEUTIC OPTION FOR PAIN MANAGEMENT AND/OR ANXIETY.”

Principal Investigator: Dr. Cooper Williams
Institution: Equine Veterinary Care for Central Maryland
Lead Investigators: **All participating attending vets to be listed**

Organization: Panacea Life Sciences
Sponsor: James W. Baumgartner, Ph.D.

USE OF CANNABIDIOL (CBD) AS AN EQUINE THERAPEUTIC OPTION FOR PAIN MANAGEMENT AND/OR ANXIETY

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

You will be provided a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

Panacea Life Sciences is working to optimize the healing power of industrial hemp products. Our mission is to optimize formulations for treating various ailments. We are dedicated to conducting clinical studies that provide better guidance for hemp-based products that include dosing guidelines and efficacy for specific conditions.

In this study, we are examining the effective use of our Equine formulation containing phytocannabinoid rich hemp oil for alleviating inflammatory pain and for reducing anxiety. You are invited to participate in this research study to evaluate the effectiveness of Cannabidiol (CBD) to manage pain associated with osteoarthritis as well as the ability of the product to reduce anxiety in your horse. Your horse has been identified by your family veterinarian as a

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potential candidate for this study. This study is being sponsored by Panacea Life Sciences, Inc. and led by Cooper Williams, V.M.D. Your family veterinarian will help guide you through the process of evaluating the effectiveness of the product. We ask that you read this form and ask any questions before agreeing to participate in this study. Before you decide, you can talk to anyone you feel comfortable with about participation in the study.

Purpose of the research

Phytocannabinoid Rich (PCR) Hemp Oil (high concentration of cannabidiol) has been shown within preclinical testing models to reduce pain, increase mobility and potentially decrease itching related to dermatitis. The purpose of this study is to determine with selected equine patients whether administration of a PCR hemp product will increase mobility and decrease pain associated with inflammatory- and/or age-related pain as well as to gather information on any additional benefits the supplement may provide.

Type of Research Intervention

This research will involve the horse owner or caregiver dosing their pet twice daily with Panacea Equine as directed. Because this study will aim to determine the optimal amount of CBD to be administered based on horse body weight, the owner or caregiver will be directed to provide specific dosing amounts (which will be described in the number of tablets to administer) to the animal. The owner or caregiver will be asked to complete an online assessment weekly through the course of the study to determine benefits as described in the research protocol.

Participant selection

We are recruiting at least fifty, (50) horses with clinical evidence of osteoarthritis or with signs of anxiety from various veterinary hospitals throughout the US. The majority of patients enrolled will not currently be receiving treatment for their osteoarthritis. Participating horses will receive the Panacea cannabidiol product at an approximate dose of 1 mg CBD/10 kg of body weight, with a select group receiving 1 mg CBD/5 kg of body weight, twice (2x) daily for two consecutive weeks. Horse owners or caregivers will be asked to use a specifically designed inventory questionnaire to assess both pain and anxiety in the animals receiving CBD. This questionnaire is extremely important to the study to evaluate the horse's response to the dietary supplement and whether the baseline condition is improved through the dosing regimen.

Owners and/or caregivers will also be asked to evaluate the patient one week prior to administering the CBD and one week following discontinuation of the product. An online survey link will be provided for you to fill out each Sunday.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at your veterinary clinic will continue, and nothing will change. If you decide not to participate in this research project, you will be offered the treatment that is routine as discussed by your veterinarian. You may change your mind later and stop participating even if you agreed earlier.

Procedures and Protocol

Cannabidiol has been reported to have a potential benefit for treating a wide range of disease, e.g., osteoarthritis, anxiety, neurologic and endocrine disease, and drug-resistant infections. We

are evaluating this product in stages to determine how best it can be utilized to improve the quality of life of patients with the conditions above as a sole agent or as an adjunct to more traditional therapies.

The objective of the study is to:

1. Evaluate the efficacy of the test product as an option for management of patients who have pain, limited mobility or a diminished quality of life secondary to osteoarthritis.
2. Evaluate the efficacy of the test product as an option to reduce the anxiety of patients through a variety of natural environmental stressors, such as transportation or stabling.
2. Assess palatability, ease of administration, and potential for side effects associated with the administration of the test product.

Duration

Participation in this study requires that pet owners administer the test product TWICE daily to their pet for two consecutive weeks. During the trial period, we ask that patients who are receiving other medications or therapies to discontinue those in order to more accurately assess the efficacy of the test product. Since this study is observational and relies on the systemized feedback from pet owners, no procedures will be performed on any patient during the study period.

Side Effects

During the course of the study, patients may experience diarrhea or lethargy. While other undesirable side effects may occur, the dose of CBD used in this study is well below doses used in other studies that established safe, tolerable doses of the product. As a consequence, should any of the side above effects occur, they should be self-limiting or resolved with a minimum amount of intervention by your family veterinarian. Patients participating in the study who have been receiving other therapies may observe differences in their pet relative to the prior therapy. Please feel free to discuss your concerns with your family veterinarian or the lead investigator at any time.

Benefits

The benefits to study participation may include but not be limited to: 1. A more comprehensive understanding of how the test product may be used to manage osteoarthritis while minimizing the potential for undesirable side effects, 2. Improved mobility, agility and freedom of movement due to pain relief for you horse provided by the test product, 3. Reduced anxiety and behavior of the animal, and 4. Contribute to the understanding of the dose-response relationship of CBD to alleviate various disease conditions in horses. In total, this study will greatly increase our understanding of the positive effects of CBD on equine health.

Reimbursements

Participating owners will be provided the test product for the duration of the study period at no cost. The test product will be shipped directly to your supervising veterinarian or caretaker who will distribute the product to you. Therefore, there are no direct costs to participating owners in

this study. In the unlikely event of side effects associated with this product, clients will be responsible for any veterinary costs incurred during the study period to treat perceived or actual side effects.

Confidentiality

All results will be confidential. Information about your pet may be used in scientific presentations and/or publication. However, no personal or identifying information about you or your pet will be released. Your pet’s record for the study may, however, be reviewed by the study’s lead investigator, Dr. Cooper Williams, to understand better your patient’s medical history and how it may pertain to the management of osteoarthritis and anxiety in this study.

Sharing the Results

The knowledge we obtain from doing this research will be shared with you through your veterinarian. Confidential information will not be shared.

Right to Refuse or Withdraw

Participation in this study is voluntary. You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. Your decision whether or not to participate in this study will be respected and will not affect your current or future relations with your veterinarian.

Whom to Contact

For any additional questions or information, please contact your attending veterinarian, or the study’s principal investigator Dr. Cooper Williams.

PANACEA EQUINE INGREDIENTS: DEXTROSE, HEMP OIL, PEPPERMINT FLAVOR, MAGNESIUM STEARATE.

PART II: CERTIFICATE OF CONSENT

I have read the preceding information, or it has been read to me. I have had the opportunity to ask questions about this project, and any questions that I had have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Client: _____

Print Name of Horse: _____

Signature of Client: _____

Date _____

Day/month/year

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness _____

Signature of witness _____

Date _____

Day/month/year

STATEMENT BY THE RESEARCHER/PERSON TAKING CONSENT

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

- 1. Panacea products to be provided and instructions on the application**
- 2. Agreement on record keeping including content and frequency.**

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent _____

Date _____