A PILOT STUDY TO INVESTIGATE THE BENEFITS OF A CANNABIDIOLIC ACID TOPICAL CREAM FOR THE TREATMENT OF RESTLESS LEG SYNDROME

Research Subject Consent Form

MARCH 2, 2024

SYNTHONICS INC

RESEARCH SUBJECT CONSENT FORM

Title: A Pilot Study to Investigate the Benefits of a Cannabidiolic Acid Topical Cream for the Treatment of Restless Leg Syndrome

Protocol # **CHYLORLS-001**

Sponsor: ChyloRelief

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24-hour Phone Number: **610-585-5998**

RESEARCH DESCRIPTION

You are invited to participate in a restless leg study. You were identified as one of ten (10) people to participants. You were contacted by phone to invite you to discuss the details of the trial, answer any questions you may have and if you agree, to get your information so you may sign this informed consent form (permission form) via DocuSign to enroll you in the study. You will receive a copy of the signed permission form via email.

The study is to see if a topical application of cannabidiolic acid (CBDA, a hemp derived molecule) based cream will reduce or relieve your restless legs. Specifically the cream is made of Chylobinoid which is a magnesium infused cannabidiolic acid (CBDa)-rich micellar complex derived from hemp extract. In addition to Chylobinoid, the cream contains Shea Butter and menthol.

You will be given, free of charge a jar of cream that contain CBDA. There is no other compensation. You will not feel any intoxicating effects (this will not get you high) because this cream is not absorbed systemically (into the body), and because CBDA doesn't sit on an area in the brain (target site) that would be intoxicating. The cream acts locally on the skin. The CBDA cream will not show up on a urine or blood test. The study will require that you use 1 teaspoon (tsp) (provided) of the cream once each night 30-45 minutes before bedtime for 2 weeks (14days) to the affected region or regions. You are encouraged to re-apply the cream using the same teaspoon measurement to the affected region if your restless legs wake you up. If you agree to participate, the entire study will be conducted in your home. You will sign the consent form first using DocuSign. Once the consent form is signed you will answer a short questionnaire over the phone before you start the study and two short questionnaires when the two weeks are over. The questionnaires will take less than 10 minutes to complete. The first questionnaire includes questions about your restless legs and how it impacts your life, and the second questionnaire will be given at the end of the study and will examine how you believe the cream impacted the

quality of your life. You will receive the cream by mail. At the completion of the study you are permitted to keep the remainder (if any) cream.

Prior to using the cream, we recommend that you perform a skin patch test at home. Use a small amount of the cream (size of a nickel) and apply it to an approximately quarter sized spot on normal skin. We recommend an area that is easily reached such as the lower part of the arm. Wait about 20-30 minutes to see if you experience a bad reaction including itching, swelling, rash, welts (raised, often red marks on the skin that can show up when someone's skin reacts to something). If you do, wash the skin immediately to remove the cream and if needed apply Vaseline or its generic or Aquaphor or its generic to soothe the skin. Please contact Dr. Kimless to inform her about your skin reaction. You will not be able to complete the study. We request, at our expense, that you return the unused container of cream to our facility. If you do not experience any bad skin reaction, then you are to begin using the cream each night for 14 days. You are to apply one teaspoon of cream, enough to cover all of the areas affected by your restless legs and massage the cream into the area (s) thirty (30) to forty-five (45) minutes before bedtime.

If you have any questions at any time, you are always able to contact Dr. Kimless by text or phone. The phone number is included with this form.

DETAILED RESEARCH CONSENT

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

What should I know about this research?

- A study team member will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this survey study is to follow your experience as you participate in a research study that will provide you with a CBDA topical cream to apply to your restless legs. About 10 subjects will take part in this research. Restless Leg Syndrome (RLS) is a condition that makes a person feel like they have an uncomfortable sensation in their legs, which can feel like tingling, creeping, or the urge to move them. It typically happens when they're resting or sitting still for a long time, like when lying in bed or sitting during a long flight. The feeling usually gets a bit better when moving the legs or walking around. It can be annoying because it can make it tough to relax or sleep well.

How long will I be in this research?

We expect that your participation in this research will last 2 weeks (14 days) of treatment beginning once you receive the cream.

What happens to me if I agree to take part in this research?

If you agree to participate in this study, you will be asked questions over the phone at the beginning of the study and at the end that need to be completed for our statistics. You will be asked restless leg specific questions and how it impacts your life, and at the end of the study you will also be asked your impression of change the cream had on your restless legs.

What are my responsibilities if I take part in this research?

If you agree to participate in this study, you will agree to use the cream every night and to answer the questionnaires.

Could being in this research hurt me?

Risks of participating in this study include:

- Skin rash, itching, swelling, peeling, or welts from the cream
- Potential eye irritation if it gets into the eye.

If you do get the cream in your eye please follow these steps:

1. **Clean Hands:** Make sure your hands are clean before you touch your eye. Wash them with soap and water.
2. **Get Comfortable:** Find a comfortable place to sit or stand near a sink.
3. **Prepare Clean Water:** Turn on the tap and adjust the water so it's lukewarm – not too hot, not too cold.
4. **Cup Your Hands or Use a Bowl:** If you can control your hand movements well, you can cup your hand and bring water to your eye. If not, you might want to fill a clean bowl with the lukewarm water.
5. **Blink in Water:** Splash some water into your eye gently,or dip your eye into the bowl of water and blink. Blinking helps to get the shea butter out.
6. **Use Clean Running Water:** If possible, position yourself so that your eye is under the stream of water from the faucet. Let the water gently run into your eye while blinking to help rinse the cream out.
7. **Repeat If Necessary:** You might need to rinse your eye for several minutes. Just make sure the water flow is gentle.
8. **Pat Dry:** Once the cream is out and your eye feels better, gently pat your eye dry with a clean towel. Don't rub your eye – just pat around it gently.
9. **Rest Your Eye:** Your eye might be a bit irritated after, so close it and rest it for a while.

If your eye still feels uncomfortable, continues to have blurry vision, or gets worse, you should go see a doctor. They can make sure everything is alright and give you more help if you need it.

In addition to this risk, taking part in this research may harm you in unknown ways in that although this cream has been used in hundreds of patients, there still could be unforeseen consequences or dangers that have not yet been recognized or reported.

Will it cost me money to take part in this research?

Taking part in this study will not cost you any money.

Will being in this research benefit me?

We cannot promise any benefits to you from your taking part in this research. Your participation in this study may benefit you and others in the future, by providing the study team with a better understanding of restless leg symptoms and its treatment.

What other choices do I have besides taking part in this research?

You do not need to participate in this survey study.

What happens to the information collected for this research?

Your private information may be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration or the Department of Health and Human Services
- The Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep your name and other identifying information confidential.
We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.
Data collected in this research might be de-identified and used for future research or distributed to another investigator for future research without your consent.
Federal law provides additional protections of your personal information. These are described in an attached document titled “Authorization to use and disclose your protected health information.”

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at Allendale IRB where you can call at 860-434-5872 or subjectrights@allendaleirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What if I am injured because of taking part in this research?

By signing this consent form, you are not waiving any of the legal rights that you otherwise would have as a participant in a research study.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- You become pregnant;
- The research is canceled by the sponsor;
- You are unable to complete the study;
- You are unable to answer the questionnaires.

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research. If I do become pregnant during the study I will withdraw immediately from the study, and inform Dr. Kimless and I will alert my primary care and/or obstetrician who will follow me during and after my pregnancy. Dr. Kimless will be available to speak with your physician regarding the cream.

What happens if I agree to be in this research, but I change my mind later?

You may decide to withdraw from the study at any time up until the point of data analysis. Once the data has been analyzed, you will no longer be able to withdraw yourself from the study.

Will I be paid for taking part in this research?

You will be provided the treatment cream for your participation. The entire study is done at home.

Statement of Consent:

Your signature documents your consent to take part in this research.

Signature of participant	Date
Printed name of participant	
Signature of person obtaining consent	Date