Informed Consent

Sponsor / Study Title:	**Phylos Bioscience, Inc. / "A Direct-to-Consumer, randomized, double-blind, placebo-controlled, double cross-over study investigating the effect of specific cannabinoid products on motivation, energy level, focus, and appetite in healthy adults "**
Protocol Number:	**PS04**
Principal Investigator:	**Noah Craft, MD, PhD, DTMH**
Telephone:	**(213) 335-3937 (24 Hours)**
Address:	**People Science** **8605 Santa Monica Blvd** **Suite 85089** **West Hollywood, CA 90069**

What is the purpose of this study?

You are invited to participate in a research study about the effect of using a unique formulation of Tetrahydrocannabivarin (THCV) on motivation, energy level, focus and appetite. The purpose of this study is to evaluate the effect of taking THCV on motivation, energy level, focus, and appetite in comparison to THC only and a placebo. A placebo looks exactly like the study product being tested but does not contain any active ingredient. Additionally, the study will be conducted using a double cross-over design, which means that you will take the study product with the active ingredient and placebo, with no active ingredient, at different times during the study. Subjects in this study will complete surveys about their experience after taking the Study Product, the THC-only Study Product, and Placebo. This study is being conducted by People Science, and is sponsored by Phylos Bioscience, Inc with Natural THCV. The information we gather may help inform how people may use this study product to increase motivation.

You do not have to join this research study and it will not affect any health or wellness services that you otherwise receive from Phylos Bioscience. If you are interested in learning more about this study, please continue to read.

What will I be doing?

There are 3 periods in this study: Screening, Baseline (your starting point) and the Study Product Use Period.

Screening Period: The screening period will consist of filling out your basic demographic information, completing a survey of your medical history and current and/or past cannabis use. This should take 2-3 minutes to complete in the Chloe app. Based on the information that you provide, you may or may not be eligible to continue with the study. You will be notified about your eligibility within two weeks of completing the screening forms.

If you are eligible based on screening, you will move on to the baseline period that can last up to 2 weeks.

Baseline Period: On the first day of the baseline period, you will be asked to complete the MEFA (motivation, energy level, focus, and appetite) Questionnaire in the Chloe app. This should take 2-3 minutes to complete.

The study product will also be processed for delivery to the address you provide. You will be asked to confirm receipt of study product delivery prior to beginning the study product use period. The delivery will include three (3) identical child-resistant bags labeled A, B, and C, one will be the Study Product with active ingredient (THCV 10mg + THC 5mg), one will be a 5mg THC-only Study Product, and one will be Placebo, which will have no active ingredient. The investigator and the study team will not know which one is which. Each bag will have a total of 3 gummies, for a study total of 9 gummies. You will be randomly (like a coin flip) assigned to start using Bag A, B, or C at Baseline to begin the first study product use period. You will then crossover twice during the study duration - (1) upon completion of Study Product Use Period 1 and (2) upon completion of Study Product Use Period 2. The order in which you will take the study products will be randomly assigned. Once you confirm receipt of study product delivery, you can proceed to the study product use period.

You will be asked during the screening period if you have familiarity with and are comfortable taking at least 10mg THC. If you answer no, you may opt to cut the gummy in half during the study product use period. If you opt to cut the gummy in half, we ask that you maintain this half dose for all 9 study product use days. This means that at the end of each study product use period, you will have 3 half gummies of group A, 3 half gummies of group B and 3 half gummies of group C left over.

Study Product Use Period: The study product use period is divided into three periods, each lasting up to 7 days for up to 21 days total. You will be given clear instructions to start with bag A, bag B, or bag C at the beginning of the period. You will then be asked to identify 3 days out of the 7 day window as your study product use days wherein you will complete a study product use session for each of the three days you choose.

For the first study product use period, you will have 7 days to take your study product. You get to decide on which 3 days you take the study product you are assigned.

Example: you can take it three days in a row or every other day. The order of the days is flexible as long as you complete 3 days of study product use within the 7 day window.

A study product use session includes the intake of a single gummy followed by 10 survey questions to be completed a few hours after consuming to assess your motivation, energy level, focus, and appetite. This survey should take about 2-3 minutes to complete. Additionally, you will be asked to answer 2 survey questions the day after study product use about how you felt and your appetite at the end of the day. This should take about 1 minute to complete. You will also be asked if you experienced any adverse reactions while taking the study product. During the study product use days, you will be asked to abstain from using alcohol and any THC-containing products.

At the end of the third study product use day, you will be asked to complete the MEFA (motivation, energy level, focus, and appetite) Questionnaire. This should take 2-3 minutes to complete. Once you complete 3 days of study product use sessions during the first period, you can immediately cross-over and begin the second study product use period the following day.

During the second study product use period, you will switch over to your next assigned bag (A, B, or C). You will be asked to do the same activities as the first study product use period. Upon completion of the third study product use day, you will be asked to complete the MEFA Questionnaire again and cross-over into your third and final study product use period the following day.

During the third study product use period, you will switch over to the third and final assigned bag (A, B, or C). You will be asked to do the same activities as the first and second study product use periods. Upon completion of the third study product use day, you will be asked to complete the MEFA Questionnaire and another survey about your experience while engaged in this study. This will take about 2 minutes to complete.

If you opt to complete all three study periods in 3 consecutive days, one after the other, you will be able to complete the entire study product use period within a minimum of 9 days. If you opt to complete all three study product use periods in non-consecutive days, you will have a maximum of 21 days to complete the entire study product use period.

What technology will I be using?

You will use the Chloe mobile application to consent and communicate with the study team. The Chloe Platform is a computer, smartphone and tablet application developed by People Science. Its purpose is to help conduct clinical research studies and support self-exploration of health and wellness. Clinical research that is conducted using the Chloe Platform application may be preferable since it provides the ability to participate in research from the comfort of your own home. Viewing of study documents and calendar, completion of surveys, and asking study related questions to the study team may be done through the Chloe Platform application.

Risks

Some questions may be personal or upsetting. You can skip them or quit the survey at any time. We ask that you notify a study team member if you no longer wish to participate in the study.

Online data being hacked or intercepted: Anytime you share information online there are risks. We use a secure system to collect this data, but we can't completely eliminate this risk.

- Breach of confidentiality: There is a chance your data could be seen by someone who should not have access to it. We are minimizing this risk in the following ways:
    - All identifying information is removed and replaced with a study ID and profile when you enroll into the study.
    - We will store all electronic data on a password-protected, encrypted computer.
- We will keep your identifying information separate from your research data. We will destroy this link after you finish collecting the data and participation in the study.

As part of this research, you may be required to use one or more of the following: a phone or web app/ site, an electronic study diary (eDiary), or a device that tracks information about you. While using these, information about you may be collected and shared with the researchers or people outside of the study. This data might include personal health information, location, call logs, text message history, web browsing history, or social media use. A complete description of the data collection and sharing for an app, eDiary, or device can commonly be found in the Terms of Use, End User License Agreement, or Privacy Policy associated with the device. If you would like to read these documents, request a copy or instructions about how to access this information from the investigator.

While the Terms of Use, End User License Agreement, or Privacy Policy may include statements limiting your rights if you are harmed as a result of your use of the app, eDiary, or device in this study, you do not release the investigator, sponsor, institution, or agents for responsibilities from mistakes. You also do not waive any of your rights as a research subject.

Cannabis Risks: Cannabis may cause side effects including:

- Drowsiness
- Headache
- Dry mouth
- Low blood pressure
- Hallucinations
- Light-headedness

You should not drive after taking this product.

High doses of cannabis may interact with drugs taken for ADHD and/or with other psychotropic medications.

Individuals who have comorbidities, including a 1) history of, or currently undergoing product use for substance abuse disorders, 2) currently pregnant, planning to become pregnant within the next month, or breastfeeding, 3) allergies to formulation ingredients, 4) current or prior psychotic disorder, 5) current or prior substance abuse disorder, 6) immunosuppressive product uses, including organ transplant subjects, active immunotherapy for cancer product use, and 7) any condition that is considered by investigator to be a contraindication to cannabis (for example specific drug-use interaction, unstable cardiac arrhythmia) should not participate in this study.

The study product is meant for you, the subject only. Please keep out of reach of children.

Possible Benefits: The knowledge obtained from your participation may help inform future product development and the use of THCV on individual motivation, energy level, focus, and appetite. This information may also help people in the future.

Estimated Number of Subjects: There will be a total of approximately 58 subjects.

How long will it take? The total amount of time on this study will be up to 7 weeks. Up to 2 weeks during screening, up to 2 weeks for baseline / study product delivery, and 3 weeks in the study product use period. The study product use period can be as short as 9 days or as long as 21 days depending on how quickly you complete your 3 sessions of each study product use.

Costs: There will be no cost to you.

Compensation: If you complete the study, you will receive a $50 gift card for your time and effort in participating in this study.

You will be paid at the end of your participation in the study.

If I don't want to be in this study, are there other options? Instead of participating, you have the option to not participate. There will be no consequence to your medical care or legal rights. The investigator or sponsor can stop your participation at any time for any reason without your consent.

Alternatives to participation: This research study is for research purposes only. The only alternative is to not participate in this study.

New findings: Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

Confidentiality and Data Security

We will collect the following personal information for the research: subject ID; full name, age, gender, zip code, e-mail, and telephone number; medical history; supplements and medications you are taking. This information is necessary so that we can better understand how the study product may improve your motivation.

Where will personal information be stored? Your personal information will be stored on secure, password-protected computers and servers to ensure the privacy of your personal information.

How long will personal information be kept? Your personal information will be kept as long as you participate in the research and have an active account with People Science.

Who can see my personal information?

We (the researchers) will have access to your personal information to understand how the study product may improve your motivation. People Science will also use your contact information so that we can compensate you for your time on this study.

Future research: De-identified data may be shared with other researchers. De-identified data means that all identifying personal information about you, including your name, email, and telephone number will be removed and will not be shared. The responsible sharing of research data for future scientific research maximizes the value of the data and helps to advance scientific knowledge. You will not be told specific details about these future research studies. If you do not want your de-identified data to be used for future scientific research, you can object to this at any time by contacting our study team. If you object to sharing de-identified data, the data will not be used for further scientific research, but this will not affect any research activities already undertaken.

Agencies that enforce legal and ethical guidelines may have access, such as:

- The Institutional Review Board (IRB)
- The Office for Human Research Protections (OHRP)

We may share our findings in publications or presentations. If we do, the results will be de-identified and aggregated (grouped) with no individual results. If we quote you, we'll use pseudonyms (fake names). While every effort will be made to protect the confidentiality of your information, absolute confidentiality cannot be guaranteed.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At

most, the Web Site will include a summary of the results. You can search this Web site at any time.

Whom to contact about this study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research subject;
- Eligibility to participate in the study;
- The Investigator's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the Investigator at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00071993.

Informed Consent Signature

By signing the electronic Informed Consent Form below, you are confirming the following:

I. I confirm that I have read and understood the information for the above study and have had the opportunity to ask questions.

II. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

III. I understand that the Sponsor of the clinical study, others working on the Sponsor's behalf, such as the regulatory authorities will not need my permission to look at my information collected in the research platform for purposes of conducting this current study and for any further research analysis.

By signing below, I agree my handwritten signature on this electronic document is the legal equivalent of my handwritten signature on a paper document.

_____

Subject's Printed Name

_____ _____

Subject's Signature Date