THIS IS AN IMPORTANT DOCUMENT – KEEP FOR FUTURE REFERENCE

PARTICIPANT INFORMATION AND CONSENT FORM

Sponsor / Study Title:	**SoberEye / "An open label pilot study evaluating the efficacy of a smart phone-based test on measuring pupillary light reflex alterations following cannabis use in healthy adults"**
Protocol Number:	24SICFP01
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You are invited to participate in a research study. Participation in this study is strictly voluntary. To make an informed decision about participating in this study, it is important that you understand the potential risks and benefits of the study. This process, known as informed consent, ensures you have all the information needed to decide. This consent form outlines the study's purpose, procedures, potential benefits, risks, and how your medical information will be handled.

Take your time to thoroughly read all the details about the study, and do not hesitate to ask any questions you may have regarding the information given and about the study. Study staff will answer all your questions. You have access to this form and can review it at your leisure before making a decision.

You should not sign this form until you fully understand the information provided, feel comfortable with your decision to participate, and have had all your questions about the study answered to your satisfaction. You will be provided with a signed copy of this form and are expected to keep it for your record. Once consent has been obtained, the study assessments will proceed.

If you wish to contact the study staff, please use the phone number or email address provided at the top of this page.

BACKGROUND AND PURPOSE

Cannabis contains substances including delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). Symptoms associated with the effects of THC may include fatigue and problems with thinking or understanding, including memory, concentration, attention and reaction time. These effects could pose serious safety risks for cannabis users.

Although legalization of recreational cannabis is increasing in North America, there is concern for workplace safety with increasing cannabis use among employees. Despite the widespread safety concerns of workplace cannabis use, tools to assess impairment are lacking.

The pupillary light reflex (PLR) involves exposing the eye to light and then assessing how the pupil reacts. There are special tools to measure PLR but are costly, which limits accessibility and widespread use.

SOBEREYE OPTOVERA is a portable, non-invasive hand-held device that measures PLR. **The objective of this study is to investigate the ability of this smart phone-based test in detecting PLR changes following cannabis use in healthy adults.** Future studies may determine if PLR changes are related to cognitive impairment or workplace performance. The device is not yet approved by Health Canada and is considered investigational.

STUDY POPULATION

This study will include 20 healthy adult males and females 21 years of age or older who are cannabis users, familiar and experienced with THC's acute effects, and have no previous history of severe negative reactions after oral ingestion of cannabis.

HOW LONG IS THE STUDY?

If eligible, your participation in this study will consist of one in-clinic visit (Visit 1) lasting approximately 9 hours.

Please note: Attending Visit 1 does not guarantee enrollment in the study. Eligibility will be assessed at the beginning of Visit 1 to determine if you meet all the study requirements to participate.

IMPORTANT THINGS TO NOTE

- You must agree to avoid using any form of cannabis for 3 days prior to the in-clinic study visit.
- You will need to arrange a designated person to provide transportation for you after the study visit. If this is not possible, the study staff can arrange transportation for you.
    - Study staff will assess you at the end of the visit to ensure it is safe for you to leave. You will remain at the study clinic until your transportation has arrived and are cleared by study staff to leave.
- To determine your eligibility to participate in this study, detailed information about your lifestyle, medications, and medical history will be collected. This information will help determine if you meet the necessary inclusion and exclusion criteria for this study.
- By signing this consent form, you are not guaranteed to be enrolled in the study. Your participation depends on meeting the study's specific eligibility criteria, which will be determined through a series of questions and assessments.
- This study will use competitive enrollment. That means when the target number of participants begin the study (20), all further enrollments will be closed. Therefore, it is possible that you

could be in the screening phase, ready to begin the study, and be discontinued without your consent if the target number of participants have already begun the study.

WHAT WILL HAPPEN DURING THE STUDY?
The following provides an overview of what will happen throughout the study.

VISIT 1 – Screening/Enrollment
Some portions of this visit may occur virtually prior to coming into clinic.

Avoid any form of cannabis use 3 days before the visit. Eat and hydrate well in the morning before coming to the visit.

After informed consent is obtained, visit assessments will include:
- Review of medical history, medications, current health status, any changes in health
- **Cannabis Use Questionnaire** which will assess your cannabis use habits
- Individuals of child-bearing potential will be required to provide a urine sample for a urine pregnancy test. You will be provided with a collection container and instructions on how to provide the sample
- Seated resting blood pressure and heart rate measurements
- Weight and height measurements. Body Mass Index (BMI) will be calculated.
- Potential eligibility will be reviewed

If you are not eligible, you will not be allowed to participate in the study. No further study specific assessments will be conducted, and you can go home.

If you are eligible, you will be enrolled and randomized into the study and undergo further assessments described below.

Randomization:
You will be assigned by chance (like flipping a coin) to a study group. If eligible, you will be randomized to 1 of 2 groups:
- 10mg of THC (Two 5 mg Cannabis oil softgels)
- 25mg of THC (Five 5 mg Cannabis oil softgels)

You will have an equal chance of being assigned to either group. This is an open-label study. This means that you, the study staff and the Sponsor will know which group you are randomized to. However, neither you, the study staff or Sponsor can choose which group you are randomized to, ensuring the integrity of the trial.

The cannabis products used in this study are purchased over the counter and are available in stores.

Before Cannabis Product Consumption:
- 50, 40, 30, 20 and 10 minutes before you consume the cannabis product, you will be asked to complete the following assessments:
  - **SOBEREYE Smart Phone-Based Test** – You will place the device and mask over your eyes and follow instructions given by the study staff. Each measurement will take about 90 seconds to complete

- **NeuroLight Pupillometer** – Study staff will use this hand-held device to measure how your pupils react and change in size. Each measurement will take about 15 seconds to complete

- Before you consume the cannabis product, you will be asked to complete the following assessments one time:
  - **Modified Drug Effects Questionnaire (DEQ-5)** – This questionnaire will be used to assess your personal experience with drug effects
  - **Dynavision Test** is a large, computerized light board that lights up in a random order and will be used to measure your reaction time. A training phase will occur to help you become familiar with the test.

Cannabis Product Consumption:

- Two or five cannabis oil softgels will be administered in the clinic to make 10 mg or 25 mg of THC, respectively, depending on which study group you are assigned to. You will need to consume all of the softgels assigned to you in order to continue in the study.

After Cannabis Product Consumption:

- 5, 30, 60, 90, 120, 180, 240, 300, 360, 420, and 480 minutes after you consume the cannabis product, you will be asked to complete the following assessments:
  - **SOBEREYE Smart Phone-Based Test**
  - **NeuroLight Pupillometer**
  - **Modified DEQ-5**
- 60, 120, 180, 240, 300, 360, and 420 minutes after you consume the cannabis product, you will be asked to complete the following assessments:
  - **Dynavision Test**
- About 120-180 minutes after you consume the cannabis product, you will be provided with lunch and snacks as needed
- Seated resting blood pressure and heart rate measurements will be taken
- Any changes in health will be assessed and recorded throughout the study visit
- You will remain in clinic until cleared to leave with a designated driver or transportation service

MEDICATIONS, SUPPLEMENTS, AND FOOD/DRINKS

If you are taking any prescribed medications, you must agree to maintain you dosing regimen during the study, unless otherwise recommended by your general/nurse practitioner. If they recommend any medication or dose changes, please notify the study staff immediately. You should not discontinue your regular medications unless explicitly instructed by your general/nurse practitioner. Stopping regular medications without medical advice to join this study may worsen your health. If you stop your regular medications, inform the study staff immediately.

- If you are taking any prescribed medications and/or treatments which may affect the study outcomes, you may only be assessed for eligibility if you have been taken off these therapies by your general/nurse practitioner. The study doctor will recommend an appropriate washout period prior to enrollment in the study.
- If you use any over-the-counter medications, supplements and/or foods and drinks which may affect the study outcomes, you must be willing to stop taking them and agree not to consume these items during the study. The study doctor will recommend an appropriate washout period prior to enrollment in the study.

Washout Period: This is a period of time recommended by the study doctor to allow restricted substances (such as medications, supplements, foods, or drinks) to clear from the body before the study begins. If you have recently taken or stopped any restricted substances or participated in activities that conflict with the study, a washout period may be required before enrollment.

BIRTH CONTROL, PREGNANCY, AND BREASTFEEDING

You must not participate if you are pregnant, breastfeeding or planning to become pregnant during the study. Individuals able to become pregnant (not post-menopausal, have had a menstrual period in the past 1 year, or have not had any of the following surgeries: hysterectomy, bilateral oophorectomy, complete endometrial ablation, or bilateral tubal ligation) must have a negative in-clinic screening/baseline urine pregnancy test and agree to use a medically approved method of birth control for the duration of the study. If you are using hormonal birth control, you must have been using it for at least 3 months prior to screening.

Some examples of approved methods of birth control include:

- Hormonal contraceptives including oral contraceptives, hormone birth control patch, vaginal contraceptive ring, injectable contraceptives, or hormone implant
- Double-barrier method
- Intrauterine devices (IUD)
- Non-heterosexual lifestyle or agree to use contraception if planning on changing to heterosexual partner(s)
- Vasectomy of partner at least 6 months prior to screening
- Abstinence and agree to use contraception if planning on becoming sexually active during the study

If you become pregnant during the study, you will be withdrawn from the study and the study doctor will follow up with you until the child's birth, collect information about your pregnancy, its outcome, and the health of your child.

CANNABIS PRODUCT INFORMATION

Cannabis Type	Sativa (Cannabis Sativa plant)
Cannabis form	Cannabis oil softgel capsule
Name and quantity of the cannabinoid(s) (mg/g or mg/unit)	THC 5 mg/capsule; CBD 0-0.34 mg/capsule
Ingredients	MCT oil, cannabis, terpenes (Alpha-Pinene, Beta-Myrcene, Beta-Ocimene, Beta-Pinene, Linalool)
Amount(s) of cannabis	10 mg or 25 mg of THC
Frequency of consumption	Once
Mode of consumption	Oral

THC – Tetrahydrocannabinol; **CBD** – Cannabidiol; **MCT** – Medium chain triglycerides; **mg** – milligrams

Directions:

- If randomized to 10mg of THC group – You will consume **two** 5mg softgel capsules
- If randomized to 25mg of THC group – You will consume **five** 5mg softgel capsules

The softgels will be taken with water. You will remain in the clinic under study staff supervision for about eight hours after consumption. You will be provided with a meal and snacks throughout the study visit and care will be taken to ensure you are transported home safely at the end of the visit by your designated driver or transportation service.

ALTERNATIVE TREATMENTS
This study is not designed to diagnose, treat, or prevent any disease. Your alternative is to not take part in the study.

ADDITIONAL SAFEGUARDS
If you need regular medical care for current medical conditions, you should continue with this medical care unless otherwise instructed by your regular physician or other healthcare professional. For your safety, you must discuss your current medical care with the study staff, as well as changes in medical conditions during the study. In addition, all new medications that are taken during the study should be reported to the study staff.

RISKS TO YOU
SOBEREYE OPTOVERA, NeuroLight Pupillometer, and Dynavision D2 are non-invasive assessments and are considered overall low risk. However, potential risks may still be present.

- The SOBEREYE OPTOVERA device may not accurately measure your pupillary light reflex. You may experience discomfort due to the light from this test and the mask may also cause minor discomfort.
- The NeuroLight Pupillometer device may not accurately measure your pupillary light reflex. You may experience discomfort due to the light from this test.
- The Dynavision D2 device may not accurately measure your reaction time. Repetitive reaching, pressing, and rapid movements may lead to strain, loss of balance, fall, and/or overexertion.

Cannabis and Your Health
Cannabis contains substances that affect the brain and body, including delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). THC causes the intoxicating effects of cannabis. CBD is not intoxicating but can still have effects on the brain.

Cannabis use has some short-term effects as well as long-term effects. When cannabis is used, it can:

- Impair your ability to drive safely or operate equipment
    - Cannabis can cause drowsiness, slow reaction times, lower your ability to pay attention and impair coordination. Using cannabis and then driving or operating equipment can result in an accident, serious injuries or death.
- Make it harder to learn and remember things
    - Cannabis can impair your thinking, concentration, memory and decision-making, and can impact your ability to perform well on the job or at school.
- Affect your mental health
    - Though cannabis can cause euphoria (a high) it can also cause anxiety or panic.
    - In rare cases, cannabis can trigger a psychotic episode (not knowing what is real, experiencing paranoia, having disorganized thoughts and, in some cases, hallucinating). The higher doses used as part of this study may increase your risk for psychotic symptoms.

- Using cannabis frequently (daily or almost daily) and over a long time (several months or years) can:
    - Hurt your lungs and make it harder to breathe, if smoked
    - Cannabis smoke contains many of the same harmful chemicals found in tobacco smoke.
    - Affect your mental health
- Frequent use of THC over a long time increases the risk of cannabis dependence, also called:
    a. Addiction
    b. Cannabis use disorder
    c. Problematic cannabis use
- It is also associated with an increased risk of developing or worsening disorders related to anxiety and depression. Thoughts of suicide are also known to increase with the heavy use of cannabis. If at any time during the study you have any thoughts of hurting yourself or someone else, you can call or text the toll-free 24-hour Suicide Crisis Helpline at 988.
- Using products with higher levels of THC (20% THC [200 mg/g] or more) such as resin, hash oil, wax and distillates further increases the risk of mental health problems over time.
- Stopping or reducing your cannabis use can improve your mental health.
- Potential side effects after using cannabis may also include: fever, nausea, vomiting, loss of appetite, abdominal discomfort.
- Adverse events related to cannabis use are more severe in persons older than 55. This means that side effects may be more common or more pronounced in older participants.

In this study you will consume cannabis; however, for the shorter duration and under supervision of our staff. Everyone's response to cannabis differs and can vary from one time to the next. You may experience any of the effects mentioned above, as well as others that are not listed. For your safety, we recommend you refrain from consuming more cannabis and avoid drinking alcohol at home after completing the study. It can take up to 12 hours for the effects of cannabis to subside. If you experience particularly unpleasant or harmful effects, seek immediate medical attention and contact our study staff.

Contact the study staff if you have questions about the signs or symptoms of any side-effects you read about in this consent form.

Inform the study staff right away if you experience any side-effect, problems with your health or the way you feel during the study, whether you think these problems are related to the study products or not. Refer to section "Whom To Contact About This Study" for instructions on what to do in case of an emergency.

ASSUMPTION OF RISKS

By signing this consent form you understand and agree to following:

- You are aware that voluntary participation in this study and/or the transportation from the clinic to your home exposes you to risk of mental impairment, psychological impairment, personal injury, permanent disability, death or other potential serious adverse consequences, including, but not limited to, accidents, negative effects and negative reactions.
- You freely accept and fully assume all such risks, dangers and hazards associated with cannabis use, study procedures and negative reactions, resulting from your voluntary participation in this study and/or the transportation from the clinic to your home.

POTENTIAL RISKS FROM E-CONSENT

You may receive a link via email/text message to download a PDF copy of this signed consent form. There may be risks of loss of privacy and confidentiality if the PDF copy of this consent form is viewed and/or stored on a personal electronic device (PED), especially if that PED is shared with other users or is lost, hacked, or subject to a search warrant or subpoena. Also, the PDF copy of the consent may not be able to be permanently removed from a PED.

WITHDRAWAL FROM THE STUDY

- You are free to choose to stop participating in the study at any time without penalty or loss of benefits to which you are otherwise entitled.
- If you decide to withdraw from the study after consuming the cannabis product, you must remain in the clinic under the supervision of the study staff until they determine it is safe for you to leave
- If the study staff finds out any non-study related information that may greatly affect your well-being (for example, information related to your health), they will share it with you immediately.

The Sponsor has the right to stop the study at any time.

The study doctor may also stop your participation in this study at any time without your consent, but the study doctor will tell you why. Reasons for this may include, **but are not limited to**:

- Refusal to undergo study visit procedures or failure to take the cannabis product as directed
- If the study doctor determines it is not in your best interest to continue
- Development of medical conditions or serious side-effects that may pose a health risk to you or the study outcomes
- The need for restricted medication(s) during the study
- If you become pregnant during the study

NEW FINDINGS

Any significant findings that become available during the study which may influence your continued participation in the study will be disclosed to you as soon as possible.

BENEFITS

- While there may be no immediate benefit to you, the results of this study will provide some of the required scientific evidence for the study products in this research study.
- Your participation in this study supports the research that is required to ensure the science behind the study products.

COSTS TO YOU

- All the tests, study products, examinations, and medical care required as part of this study are provided at no cost to you, the public health plan, or your private medical insurance. All costs will be paid for by the Sponsor of this study.
- You, the public health plan, or your personal medical insurance (if any) should continue to pay for expenses for your current medical care and/or prescriptions. These expenses will not be paid as part of your participation in this study.
- The Sponsor of this study is paying your study doctor for the time, effort, and expenses to conduct this study.

COMPENSATION FOR PARTICIPATION

For your time and participation in the study, you will receive a total compensation of $150 if you are enrolled and successfully complete the entire study, including all required assessments and procedures.

Upon completion of the study, you will receive a Clincard, which can be used like a prepaid Mastercard. It can be used anywhere that accepts Mastercard, or the funds can be withdrawn from an ATM (ATM fees apply). Processing times may apply before funds become available on your Clincard.

Once enrolled, if you or the study doctor determine that you are unable to complete all required study visits and assessments, you will not be eligible for compensation.

COMPENSATION AND TREATMENT FOR INJURY

In case of an injury or illness suffered while, and solely as a result of, participating in this study, you will receive appropriate medical care. The Sponsor will cover necessary medical costs not covered by the provincial health plan or your private medical insurance (if any). By signing this form, you are not giving up your legal rights, nor releasing the study doctor or Sponsors from their legal and professional obligations. Be aware that the provincial health plan or your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

CONFIDENTIALITY OF RECORDS

- Staff at KGK Science (the contract research organization managing this study) will keep all your medical information confidential to the extent permitted by law.
- All research data (health information, past medical history, and test results from this study) will be kept in a locked file. Forms on which your information is entered will not contain your name (except for the study intake form and/or external requisitions if applicable)
- Any of your personal information that is stored electronically will be password protected, accessible only to authorized personnel and coded wherever possible. Electronic data may be stored on secure servers which are physically located in Canada and/or the United States.
- You will not be identified in any publication that might result from the study. Unless required by law, only the following may have access to confidential study data (not your personal information) at the study site:
    - The study doctor and study staff
    - The Sponsor (including its monitors and auditors)
    - Members of the Research Ethics Board - Univo REB (an independent ethics committee that reviewed the ethical aspects of this study to help ensure that the rights and welfare of participants are protected and that the study is carried out in an ethical manner)
    - Government regulatory authorities including Health Canada and other foreign regulatory agencies.
- Study records will be kept by the sponsor for at least two years after the day on which the study ends and records related to adverse reactions will be retained for at least 15 years after the day on which they are prepared.
- Information from this study will be submitted to the Sponsor. Information sent from the study site will not contain your name.
- You have the right to check your study records and request changes if the information is incorrect.

- While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.
- 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 study doctor.
- 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 participant.

By signing and dating the consent form, you give your consent to collect, use and disclose your health information as described above.

A description of this clinical trial will be available on https://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.

FUTURE USE OF DATA

- Your personal information collected during this study may be stored and used for future research. If so, any personal identifiers will be removed so that the information cannot be linked back to you. As a result, we will no longer be able to identify you.
- Study doctors, including study doctors from collaborating institutions, can request this data for new research. Data may also be shared with outside non-profit academic study doctors as well as with for-profit study doctors or commercial entities, with whom we collaborate.
- You will not be asked to provide additional informed consent for the use of your de-identified information in future research.

FUTURE CONTACT

By participating in this study, you agree that the study staff may contact you in the future should additional information be needed. This contact would only occur if more data is required after you have completed the study or the study has concluded/expired. Any additional information gathered will be handled with the same confidentiality and privacy protections outlined in this consent form. You may choose not to provide additional information if contacted in the future, without any penalty or effect on the care or benefits you receive.

WHOM TO CONTACT ABOUT THIS STUDY

You can contact the study staff via email or by telephone listed on the first page of this document 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 participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study and please inform the KGK Science study staff.

A research ethics board (REB) is an independent committee that helps to protect the rights and welfare of research participants. If you have any questions about your rights and welfare as a research participant, or have concerns or complaints regarding this research study, please contact Univo REB at (919) 910-7743 or via email at info@univo-group.com.

VOLUNTARY CONSENT TO PARTICIPATE

By signing and dating this document I agree that I have been given enough time to read and consider whether to participate. I have read and understand all pages of the consent form and information it contains regarding this study in a language I understand. I have been given the opportunity to ask all my questions regarding the study with answers to my satisfaction. I understand that I may consult with the study doctor or the study staff, should anything become unclear or if I have further questions.

I volunteer to be in this study at my own free will and without being pressured by the study doctor or the study staff knowing I have the opportunity to leave at any time without giving a reason and without affecting my health care. I understand that if I choose to withdraw from the study, I must notify the study staff. The risks involved with participating in this study are clear to me. I agree to follow the study instructions provided to me by the study staff and understand I must not participate in another study while I am enrolled in this study.

I understand that I am required to arrange a responsible designated driver to transport me home after the study visit, or the study staff will help provide a transportation service.

It is clear to me that my data derived from this study will be kept anonymous and may be reviewed by the Sponsor, their agents, the Research Ethics Board, Health Canada and other foreign regulatory agencies. I understand that all my personal information will be treated as strictly confidential, except where disclosure is required by law, and will not be made publicly available; however, absolute confidentiality cannot be guaranteed.

By signing and dating this document, I do not waive any of my rights under the law or release the study doctor or Sponsor from their legal and professional obligations.

I understand that I am expected to save a copy of this signed and dated consent form to keep for my record.

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IN THE EVENT THAT ELECTRONIC CONSENT IS NOT AVAILABLE:

By signing this informed consent document, you acknowledge that you have read and fully understand all pages of the information presented in it, had enough time to consider this information, had an opportunity to ask questions, and voluntarily agree to be in this study.

_____
Printed Name of Participant

_____ _____ _____AM/PM
Signature of Participant Date (MMM,DD,YYYY) Time (HH:MM)

FOR PERSON EXPLAINING CONSENT

I attest that the participant had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

_____
Printed Name of Person Explaining Consent

_____ _____ _____AM/PM
Signature of Person Explaining Consent Date (MMM,DD,YYYY) Time (HH:MM)

FOR ELECTRONIC CONSENT:

For electronic consent, your name, digital signature, date and time of consenting will be added below by the consenting software. By adding your electronic signature, you consent to the material provided as if you were physically signing a hard copy of this document. **By signing this informed consent document, you acknowledge that you have read and fully understand all pages of the information presented in it, had an opportunity to ask questions, and voluntarily agree to be in this study.**

Participant
I voluntarily agree to participate in this study.
↓

Delegated Study Staff
I attest that the participant had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.
↓