PARTICIPANT INFORMATION AND CONSENT FORM

Sponsor/Study Title:	Chobani® / "A randomized, triple-blind, comparator-controlled, cross-over clinical trial to explore the efficacy of two investigational products on post-exercise hydration in recreationally active healthy adults"
Protocol Number:	25CHKGC01
Principal Investigator: ***(Study Doctor)***	David Crowley, MD
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Making an Informed Decision

You are invited to participate in a clinical 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 if you will participate in the study. 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 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.

Use the phone number or email address listed at the top of this page to contact study staff.

Background and Purpose

During exercise, the body loses water and electrolytes (sodium, potassium and other minerals) mainly through sweat which can lead to dehydration. Dehydration reduces blood volume, venous return (return of blood to the heart through the veins), and cardiac output (how much you're your heart pumps through the body in a minute) and may slow cardiovascular recovery after exercise. Maintaining proper hydration before and after physical activity is important to help prevent heat-related conditions such as heat exhaustion or heat stroke.

Traditional rehydration strategies often involve drinking water or carbohydrate–electrolyte sports drinks, such as Gatorade) However, water alone may not adequately restore fluid balance. While carbohydrate–electrolyte beverages can replace fluids and electrolytes/essential minerals), they often contain high levels of sodium. Regular consumption of high-sodium drinks may increase the risk of high blood pressure and other cardiovascular concerns, especially in individuals who are not athletes. Therefore, there is a need for safe and effective alternative hydration strategies.

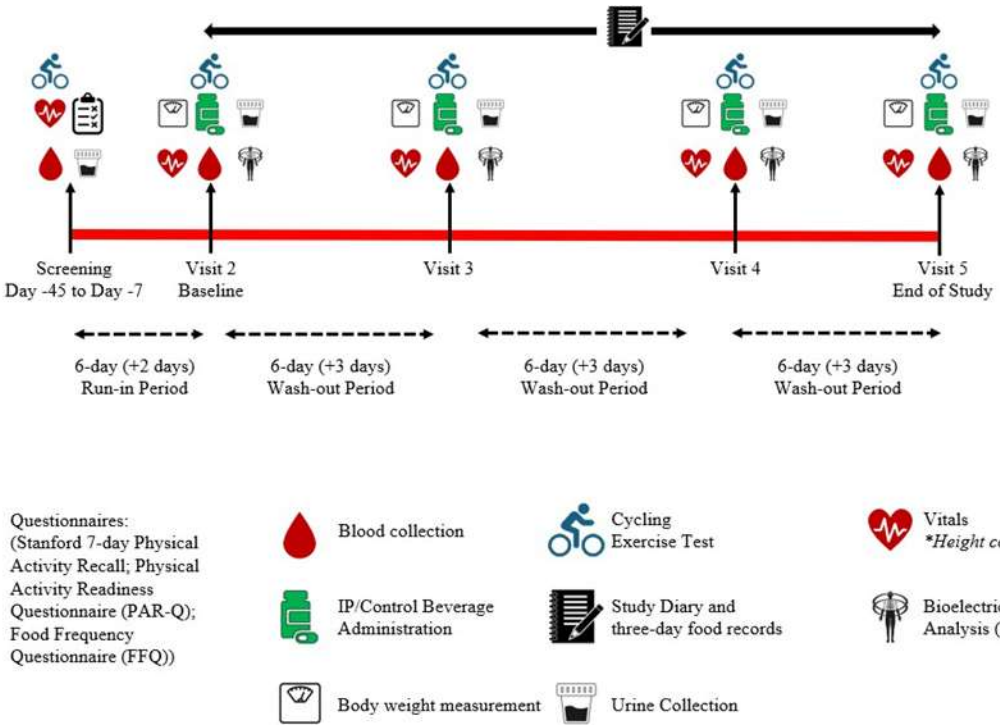
The purpose of this study is to assess the effectiveness and safety of new potassium/essential mineral-based beverages for supporting post-exercise hydration in healthy active adults versus water or marketed Gatorade.

Study Population

This study will include approximately 32 healthy males and females between 18 to 65 years of age.

How Long Is the Study?

If eligible for the study, your total participation will last approximately 29 days. This includes 5 in-clinic visits, a 6 to 8-day run-in period between Visit 1 and Visit 2, and a 6 to 9-day washout period between each of Visits 2 to 5.



*IP = investigational or study product

Study Design

The study design describes the plan for how the study is conducted. This is a *randomized, triple-blind, comparator-controlled, cross-over* study.

Randomized — During Visit 2, if you are eligible to participate, you will be randomly assigned by chance (like flipping a coin) to 1 of 4 study groups indicating the order in which you will receive each of the study products:

- Product 1 → Product 2 → Product 3 → Product 4
- Product 2→ Product 4 → Product 1 → Product 3
- Product 3 → Product 1 → Product 4→ Product 2
- Product 4→ Product 2 → Product 3 → Product 1

Neither you nor the study staff will be able to choose which group you are in, ensuring that the random assignment is fair and unbiased.

Triple-blind — Neither you, the study staff, nor the researchers analyzing the data will know which group you have been assigned to. However, if needed for your safety, the study staff can find out this information.

Crossover — You will start the study by receiving one of the 4 products. At future study visits, you will receive the other 3 products based on the order for the group to which you were randomized. A washout period will be included between the 4 study visits in which you take the study product. A washout period is a specific amount of time to allow substances to clear from the body. This design allows researchers to compare the effects of all 4 products within the same person.

Important Things to Note

General

- 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 uses competitive enrollment. This means that once 32 participants have enrolled and started the study, no additional participants will be accepted. Therefore, if you complete the screening phase and are found eligible, you may still be withdrawn from the study without your consent if the enrollment limit has already been reached. Since no official study enrollment would take place, you would not be eligible for study compensation.

Study-Specific

If you voluntarily agree to participate in this study, you must be willing to:

- Perform in-clinic exercises (cycling exercise test) as instructed by the study staff.
- Maintain a low-sodium and low potassium diet for the duration of your participation in the study, including during the run-in period. The run-in period is the time between Visit 1 (Screening) and Visit 2 (Baseline).
- Be willing to fast/no consumption of food for at least 8 hours prior to Visits 2, 3, 4 and 5.
- Collect urine samples for pregnancy tests (if applicable) at Visits 1, 2 and 5.
- Comply with dietary guidelines and study requirements prior to and during in-clinic visits.

- Complete questionnaires, records, and diaries associated with the study and complete all study visits.
- Provide urine samples at Visits 2, 3, 4 and 5.
- Avoid caffeine (for example, tea, coffee, energy drinks) and physical exercise on the morning of each in-clinic visit.
- Avoid alcohol consumption for 48 hours prior to each in-clinic visit.
- Avoid THC consumption for 3 days prior to study participation and abstain for the duration of the study.
- Avoid vigorous physical activity for 24 hours prior to each in-clinic visit.
- Maintain current lifestyle habits (such as diet, physical activity, medications, supplements, and sleep) throughout the study.
- Fully consume one bottle (591 ml) of the study product within 10 minutes and in the presence of clinic staff during in-clinic visits.

What Will Happen During This Study?

The following section provides an overview of the assessments, procedures, and schedule of study visits.

Assessments and Procedures

Blood Samples – Visits 2, 3, 4 and 5

- The total blood volume collection will be approximately 280 mL (approximately 19 tablespoons), over the period from Baseline (Visit 2) to the end of the study (Visit 5) (approximately 25 days). At any study visit, blood volume collected is not expected to exceed 70 mL (approximately 5 tablespoons). Additional blood samples may be collected during the study if necessary, such as in cases of abnormal test results or processing errors, to conduct or repeat laboratory tests.
- At Visits 2, 3, 4 and 5 an intravenous catheter (thin tube inserted into a vein temporarily for blood draws to avoid repeated sticks) will be placed to help facilitate multiple blood draws. The catheter will be flushed with a small amount of saline solution to keep it clear and working properly throughout the visits. Conventional phlebotomy (blood draw from a vein using a needle) will also be used in this study.

Urine Samples – Visits 1 (if applicable), 2, 3, 4 and 5

- 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 instructed on how to provide the sample at Visits 1, 2 and 5.
- You will be asked to empty your bladder before drinking 500 mL of low-mineral water 1 hour before your study visit, and your urine will be collected from the start of the visit until the cycling exercise test at Visits 2, 3, 4 and 5.
- After the exercise test, your urine will be collected at regular intervals over approximately 8 hours (about every 1–3 hours), and you will be asked to empty your bladder at the end of each collection period at Visits 2, 3, 4 and 5.

Food Records

- You will report your food and drink intake in a 3-day food record which you will complete before Visits 2, 3 ,4 and 5. You will complete these 3-day food records on two weekdays and one weekend day.

Study Diary

- You will complete an online daily study diary throughout the study. Questions about, lifestyle habits and any changes in medications and/or health will be included.

Bioelectrical Impedance Analysis (BIA)

This assessment will be carried out and fully explained by trained clinic staff upon your arrival at the clinic. BIA is a non-invasive method used to estimate body composition, such as body fat and muscle mass. It works by sending a very small electrical current through the body and measuring how easily it travels through different tissues. The procedure is painless and typically involves standing on or holding a specialized device. This will be conducted at Visits 2-5.

Cycling Exercise Test -Visits 1, 2, 3, 4 and 5

- This test is used to assess your ability to complete vigorous exercise. You will ride an exercise bike for 30 minutes at a level that aims to reach 70–90% of your predicted maximum heart rate. Your target heart rate will be calculated using a standard formula, and clinic staff will monitor your heart rate throughout the test to help you stay within the target range. This bicycle test does not include electrocardiogram monitoring and is not intended to diagnose any underlying heart or blood vessel problems.

Stanford 7-Day Physical Activity Recall - Visit 1

- This questionnaire assesses your levels of all physical activity from light to very hard. Questions about the type and amount of activity you performed over the past seven days will be asked, and you will also be asked whether this activity is usual for the past three months.

Physical Activity Readiness Questionnaire (PAR-Q)- Visit 1

- This screening questionnaire helps determine if it is safe to begin or increase physical activity or if medical clearance is needed before participating.

Food Frequency Questionnaire (FFQ) -Visit 1

- This questionnaire assesses your usual intake of high-sodium food and beverages.

Standardized Meals and Dietary Guidelines

Prior to in- clinic visits (at home):

- You will eat a low-sodium and low-potassium standardized meal for dinner prior to in-clinic Visits 2, 3, 4 and 5.
- Consume one bottle of low-mineral water within two hours of sleep the night before and one bottle of low-mineral water one hour before the visit 2, 3 ,4 and 5.

During in-Clinic Visit:

- Consume one bottle of low-mineral water prior to in-clinic exercises.
- You will consume identical meals (breakfast and lunch)—including the same portions—at Visits 2, 3, 4 and 5

Low Sodium and Low potassium Intake tips:

- Cook your meals at home whenever possible instead of eating out.
- Avoid adding extra salt to your food at the table. Use herbs, spices, or citrus to enhance flavor.
- Read nutrition labels on packaged foods. Choose items that contain less than 15% of the daily value for sodium and look for reduced-sodium products or foods with no added salt.
- Consume a variety of whole, minimally processed foods, and limit consumption of highly processed or ultra-processed foods.
- Avoid canned soup, high-sodium snack foods (potato chips, pretzels, tortilla chips, cheezies, etc.), fast food (hamburgers, french fries, pizza, etc.) and processed meats (hot dogs, deli meat, etc.)

Low-Sodium and Potassium Meal and Snack Ideas:

- **Breakfast:** Greek yogurt with mixed berries and granola or steel cut oats with almond milk and sliced banana
- **Lunch:** Mixed green salad with roast chicken breast, homemade vinaigrette, and goat cheese or homemade soup
- **Dinner:** Broiled salmon with brown rice and bok choy and roast chicken with steamed broccoli
- **Snacks:** Fresh fruit and vegetables

Schedule of Study Visits

You are required to fast/no consumption of food for at least 8 hours prior to each of the scheduled study Visits 2, 3, 4 and 5.

Visit 1 – Screening (Day -45 to Day -7) *Some portions of this visit may occur virtually*
• Informed consent obtained • Review of medical history, medications, current health status, and any changes in health • Urine pregnancy test (if applicable) • Seated resting Blood Pressure (BP) and Heart Rate (HR) measurements • Weight and height measurements (Body Mass Index (BMI) calculation) • Administration of the Stanford 7-Day Physical Activity Recall, Physical Activity Readiness questionnaire (PAR-Q) and Food Frequency questionnaire (FFQ) • Low mineral water for consumption and 3 Day food records (3DFR) will be provided • Complete exercise challenge • Potential eligibility will be assessed

Prior to visit 2, you will be instructed to adhere to a low-sodium and low-potassium diet during a 6-day (+2 days) washout period.

Visit 2- Baseline

- Return to the clinic with completed 3DFR
- Clinic staff will review medical history, medications, current health status, any changes in health, 3DFR and your compliance (you have been following directions) to study reminders and dietary guidelines
- Urine sample collection (if applicable for pregnancy test)
- Seated resting BP and HR measurements before and after exercise
- If you are eligible and still meet all study requirements, you will be randomized (assigned to a study group) and enrolled into the study
- Dispense standardized breakfast and bottle of low-mineral water
- Completion of exercise challenge
- Study product administration
- Blood collection, urine collection, body weight measurements, and BIA pre-exercise and at 30 minutes, 2 hours, 4 hours and 8 hours after exercise
- Standardized lunch after 3 hours post-exercise
- Low mineral water for consumption, study diary and 3DFR will be provided
- Record time of bowel movements (if applicable)

Prior to Visits 3 and 4, you will be instructed to adhere to a low-sodium and low-potassium diet during a 6-day (+3 days) washout period.

Visit 3 and Visit 4

- Return to the clinic with completed 3DFR
- Clinic staff will review medical history, medications, current health status, any changes in health, 3DFR and your compliance (you have been following directions) to study reminders and dietary guidelines
- Seated resting BP and HR measurements before and after exercise
- Standardized breakfast and bottle of low-mineral water will be provided
- Completion of exercise challenge
- Study product administration
- Blood collection, urine collection, body weight measurements, and BIA pre-exercise and at 30 minutes, 2 hours, 4 hours and 8 hours after exercise
- Standardized lunch after 3 hours post-exercise
- Low mineral water for consumption, subject diary and 3DFR will be provided
- Record time of bowel movements (if applicable)

Prior to visit 5, you will be instructed to adhere to low-sodium and low-potassium diet during a 6-day (+3 days) washout period.

Visit 5
• Return to the clinic with completed 3DFR • Clinic staff will review medical history, medications, current health status, any changes in health, 3DFR and your compliance (you have been following directions) to study reminders and dietary guidelines • Urine sample collection (if applicable for pregnancy test) • Seated resting BP and HR measurements before and after exercise • Standardized breakfast and bottle of low-mineral water will be provided • Completion of exercise challenge • Study product administration • Blood collection, urine collection, body weight measurements, and BIA pre-exercise and at 30 minutes, 2 hours, 4 hours and 8 hours after exercise • Standardized lunch after 3 hours post-exercise • Record time of bowel movements (if applicable)

Medications, Supplements, and Food/Drinks

Prescribed Medications

- You must continue taking any prescribed medications as directed by your healthcare provider throughout the study, unless they advise otherwise. Do not stop any regular medications in order to join the study unless explicitly instructed by your healthcare provider. Stopping regular medications without medical advice to join this study may pose serious health risks. If your healthcare provider recommends any new medication, changes to your current medication dose, or stopping a medication, notify the study staff immediately.
- If you are taking any prescribed medications or treatments that could interfere with the study's outcomes, you may only be assessed for eligibility after your healthcare provider has discontinued those therapies. In such cases, the study doctor will recommend an appropriate washout period before study enrollment.

Over-the-Counter (OTC) Products, Supplements, and Foods/Drinks

- If you regularly use any OTC medications, supplements, and/or consume foods or drinks that may impact study results, you must be willing to stop them for the duration of the study.
- The study doctor will let you know if these items require discontinuation and will recommend an appropriate washout period before study enrollment if needed.

Washout Period – A specific amount of time recommended by the study doctor to allow restricted substances (such as medications, supplements, foods or drinks) to clear from the body before beginning the study. 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

The effect of the study product on pregnancy and breast milk is not known. 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 Visit 1, 2 and 5 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 must stop taking the study product immediately and contact the study staff. 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.

Since the study product is investigational, there may be other risks that are unknown. Additionally, there may be unknown risks to a pregnancy, embryo, or fetus if you become pregnant.

Study Product Information

The study product will be in liquid form.

Name of study product:

IP1: Potassium 15

Medicinal Ingredient	Quantity (in g)
Acid Whey	181.4

Non-medicinal ingredients: Apple juice, mango juice, monk fruit juice, beta-carotene (for color), citric acid, ascorbic acid, sodium citrate, natural flavors.

IP2: Potassium 10

Medicinal Ingredient	Quantity (in g)
Acid Whey	121.9

Non-medicinal ingredients: , apple juice, mango juice, monk fruit juice, beta-carotene (for color), citric acid, ascorbic acid, sodium citrate, natural flavors.

Comparator: Gatorade Fruit Punch
Non-active ingredients: Water, sugar, dextrose, citric acid, natural flavours, salt, sodium citrate, monopotassium phosphate, modified food starch, colour, caramel colour, glycerol ester of rosin, Red 40

Placebo: Plain water
Active Ingredient: Water

Directions:

- You will be asked to fully consume one bottle (591 mL) of the study product immediately after completing the exercise, within 10 minutes, and in the presence of clinic staff.
- You will have to consume 100% of the study product.

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 including supplements and natural health products (NHPs) that are taken during the study must be reported to the study staff.

Risks To You

It is possible that you could have problems or side effects from the study product that nobody knows about yet. Because the investigational products contain acid whey (a milk-derived ingredient that naturally contains lactose and milk proteins), some risks are those typical of milk-derived foods. There may be unknown risks with taking the study product. Potential side-effects of taking the study product may include:

- Gastrointestinal disturbances (abdominal discomfort, bloating, gas, stomach cramps, diarrhea)
- Nausea
- Dislike of the taste

Some risks associated with blood collection may include pain, bruising, and infection at the site. Alcohol swabs and proper blood collection procedures will be followed to minimize the risk of infection. Fainting during a blood draw can occur, though it is not common. Please advise the study staff if you normally faint with blood draws.

A possible risk of the exercise challenge is muscular pain or musculoskeletal injury (such as muscle or joint strain). Exercise testing is otherwise generally safe, but because it places stress on the heart, it may cause symptoms such as shortness of breath, fatigue, dizziness, or chest discomfort; less commonly, it can trigger abnormal heart rhythms, changes in blood pressure, or reduced blood flow to the heart (angina), and in rare cases may lead to fainting, injury from a fall, heart attack, or cardiac arrest.

Could I Have an Allergic Reaction?

It is possible for people to have allergic reactions to the study product. If you have a serious allergic reaction, it could be fatal. Read the study ingredients carefully to make sure you are not allergic to any of them. Some effects of an allergic reaction that could be a sign of a life-threatening (anaphylaxis) include:

- Rash
- Difficulty of Breathing

- Wheezing
- Sudden drop in blood pressure (making you feel dizzy or lightheaded)
- Swelling around the mouth, throat, or eyes
- Fast pulse
- Sweating

If you experience any of the above-listed effects or any other side effects during the study, you should get medical help or go to the emergency room immediately and then contact the study staff. Refer to section "Whom to Contact About This Study" for instructions on what to do in case of an emergency.

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-effects, 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.

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

- Your participation in this research is strictly voluntary. You have the right to choose not to be in the study or leave at any time, for any reason, without affecting your relationship with the study doctor or study staff and without penalty or loss of benefits to which you are otherwise entitled.
- You may be asked to undergo some final visit procedures. These may include returning to the clinic to provide a final blood sample to test your markers of general health and any end-of-study assessments or questionnaires.
- If the study doctor or study staff finds out any 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 the study at any time without your consent, but you will be informed about the reason. Reasons for this may include, but are not limited to:

- Missing scheduled study visits
- Not taking study product as directed
- Not completing required assessments or procedures
- 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 clinical 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 be compensated a total of $800 if you complete the entire study and all associated requirements.

You will receive your compensation after completion of the study on 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). Compensation will be processed and received approximately 20 business days from the date you complete the study. Processing times may apply before funds become available on your ClinCard.

If you are enrolled (completed visit 2 and received study product), the compensation breakdown is as follows:

- Visit 1 (Screening): $0
- Visit 2: $150
- Visit 3: $180
- Visit 4: $220
- Visit 5: $250

Once enrolled, for any case in which you or the study doctor determine you cannot complete all the study visits and assessments, you will receive compensation for the visits you have completed. An early termination visit will be requested where you will bring back all study-related materials and be requested to complete some blood work and visit procedures if you consent to doing so. If you complete the early termination visit, you will be compensated $50.

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 secured location or server. 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.
- While the Sponsor will not have access to your personal identifying information, the study doctor, study staff, monitors, auditors, REB, and regulatory authorities may review study records, which could include your personal identifying information (such as the signed consent form) for compliance and verification purposes.
- All study data will be archived for a minimum of 15 years from the date of completion of the study in accordance with Health Canada regulatory requirements.
- 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 them or 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 specifically related to your participation in this study were 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 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 provided enough time to read and consider whether to participate. I have reviewed and understand all pages of the consent form and information it contains regarding the 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 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 may not participate in another study while I am enrolled in this study.

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, 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 keep a copy of this signed and dated consent form for my record.

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)

I attest that the participant named above 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 the pages of the information presented in it.

Participant – I voluntarily agree to participate in this study

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