PARTICIPANT INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

STUDY TITLE: A randomized, double-blind, placebo-controlled, parallel clinical trial to investigate the safety and efficacy of MB-1 on metabolic health in overweight and obese adults

PROTOCOL NO: 25ARCCM01

STUDY DOCTOR: David Crowley, MD

STUDY SITE: KGK Science Inc.
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TELEPHONE: 519-438-9374 (24 hours)

SPONSOR: Arrae

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. 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 can review this form 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 records. 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.

KEY INFORMATION

Things you should know:

- The purpose of this study is to investigate the safety and efficacy of a dietary supplement, MB-1, on metabolic health in overweight and obese adults.
- If you choose to participate in the study, you will be asked to attend 3 study visits and engage in two touchpoint calls, take the study product as directed, have blood samples drawn, have vital signs measured, complete study assessments (DEXA scan, questionnaires and

anthropometric measurements), and complete an online study diary. Your participation will last approximately 84 days.
- Risks or discomfort from this research include those from the study product such as gastrointestinal discomfort, liver trouble, and symptoms of hypoglycemia.
- As with routine blood draw, there is a small change of minor bruising or, rarely, infection at the needle site; this risk is minimized as all blood samples are collected by a qualified healthcare professional using standard, safe, blood collection procedures.
- There are no direct benefits to you from participating in this study.
- This study is no designed to diagnose, treat, or prevent any disease. Your alternative is to not take part in the study.

Background And Purpose

Obesity is a common and serious health condition associated with an increased risk of health problems such as heart disease, joint pain, sleep apnea, and reduced quality of life. Because current lifestyle, medical, and surgical treatments can be difficult to maintain and carry risks, safer and more sustainable weight loss options are needed to address the growing worldwide obesity epidemic.

The purpose of this study is to investigate the safety and efficacy of a dietary supplement, MB-1, on metabolic health in overweight and obese adults. MB-1 contains African mango seed, *Cissus quandrangularis* extract, Grains of Paradise, *Bifidobacterium Lactis* (*B. lactis*) M420, caffeine, Green Tea extract, Vitamin B6, and Chromium Picolinate—ingredients that have each been previously studied for their effects on metabolic health. The study product is not approved by Health Canada and is considered investigational.

Study Population

This study will include 120 healthy males and females, 18 to50 years old, inclusive, who are overweight and obese.

How Long Is The Study?

If you are eligible after the screening/enrollment visit, your participation in this study will last approximately 84 days.

Study Design

The study design describes the overall plan for how the study is conducted. This is a *randomized, double -blind, placebo controlled, parallel* study.

- **Randomized** — If you are eligible to participate, you will be randomly assigned by chance (like flipping a coin) to 1 of 2 study groups:
  - MB-1 group
  - Placebo group

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.

- **Double -blind** — Neither you nor the study staff will know which group you have been assigned to. However, if needed for your safety, the study staff can find out this information.
- **Placebo controlled** — A placebo is an inactive substance that looks like the MB-1 capsules but has no active ingredients. It is used in research to help determine whether the product that is being studied has real effects beyond what might happen by chance or expectation.
- **Parallel** — You will be randomised to one of the two groups and you will stay in the same group for the entire study. For example, if you are assigned to the MB-1 group or placebo group, you stay in that group throughout the entire study.

Study Product Information

MB-1 and placebo will be in capsule form.

MB-1

Active Ingredient	**Quantity per capsule**
Vitamin B6 (as Pyridoxal 5-Phosphate)	2.5 mg
Chromium (as Chromium Picolinate)	0.25 mg
Green tea extract (*Camellia sinensis,* standardized to 98% polyphenols, 50% EGCG, 80% Catechins)	100 mg
Green tea extract (*Camellia sinensis*, 92% ± 2.5 caffeine)	42.5 mg
African mango seed (*Irvingia Gabonensis*, standardized to ≥ 7% albumins 0.9-1.44% ellagic acid)	135 mg
Cissus leaf extract (*Cissus Quadrangularis*; standardized to ≥ 2.5% ketosterones)	150 mg
Grains of paradise seed extract (*Aframomum melegueta*, standardized to ≥12.5% 6-Paradol)	20 mg
Bifidobacterium animalis subsp. *lactis* B240	12.5 mg
Non-active ingredients: Rice hulls (ground), Hypromellose Capsule	

mg – milligrams

Placebo

Ingredients: white rice flour, Caramel brown E 270, Hypromellose capsule

Directions:

- You will take two study product capsules every morning with a meal for the duration of the study, starting on Day 1 (day after Visit 1) until the day before your end of study visit.
- If you forget to take the product, take it as soon as you remember on the same day
- Do not take more than one dose (two capsules) daily
- You will save all unused and open study product packaging and return them to the clinic at Visit 2 and Visit 3 to check if you have been taking them as instructed.
- Store the study product at room temperature and do not expose it to direct sunlight or heat.
- This study product may contain monopotassium phosphate, potassium phosphate, sucrose, rice hulls (ground), hypromellose capsule. If you are allergic to any of these ingredients, please notify the study doctor.

Important Things To Note

- 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 120 participants have enrolled and started the study, no additional participants will be accepted.
- If you voluntarily agree to participate in this study, you must be willing to:
  - Fast for at least 12 hours prior to Visit 1 and Visit 3 (*No food or drinks except water*)
  - Undergo a Dual-Energy Absorption X-Ray Scan (DEXA scan) at Visit 1 and Visit 3
  - Complete questionnaires, records and diaries associated with the study and complete all study visits
  - Maintain current lifestyle habits (such as diet, medications, supplements, and sleep) throughout the study
  - Engage in 20–30 minutes of light physical activity (such as walking) each day for the duration of the study starting on Day 1 and throughout the duration of their study participation until the day prior to your end of study visit.
- You should not participate in this study if:
  - You have metal implants in the spine, hip, or limbs—such as joint replacements, rods, screws, or plates.
  - Someone who lives with you under the same roof is currently participating in this study.

What Will Happen During the Study?

Below is an overview of the study assessments, procedures, and the schedule of study visits.

Assessments and Procedures

Blood Samples – Visits 1 and 3

- The total blood volume collection will be approximately 10 mL, over the period from screening/baseline (Visit 1) to the end of the study (Visit 3) (approximately 87 days). At any study visit, the blood volume collected is not expected to exceed 5 mL. 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.

All samples will be sent to an external laboratory for analysis at the end of each day. Samples will be kept for 48 hours in the lab and then discarded according to the standard procedures of the laboratory. To protect your privacy, samples will be coded and all personal identifiers will be removed so that the information or samples cannot be linked back to you. As a result, we will no longer be able to identify you.

Urine Samples – Visits 1 and 3 or Early Termination Visit

- 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.

Dual-Energy X-Ray Absorption (DEXA) Scan – Visits 1 and 3

- This test uses X-rays to assess body composition. The amount of radiation used in the DEXA scan is extremely small. The estimated amount of exposure from participation in this study will be comparable to that of a single east-to-west coast flight within the USA and similar to the normal background radiation received over the course of a single day.

Appetite, Satiety and Craving Likert Scales – Visit 1 and weekly in your dairies

- This questionnaire will assess your appetite, satiety (feeling of fullness) and craving over the past week.

Energy Likert Scales – Visit 1 and weekly in your diaries

- This scale will assess your energy levels over the past week.

Anthropometric Measurements – Visits 1, 2 and 3

- Study staff will take measurements to assess your waist circumference, hip circumference, waist/hip ratio.

Food Records

- You will report your food and drink intake in a 3-day food record which you will complete in the week immediately following the Screening/Baseline visit and during the week leading up

to Visit 2 and Visit 3. 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 study product use, lifestyle habits and any changes in medications and/or health will be included. You will also be asked to record your daily physical activity. You will also complete weekly appetite, satiety, energy, and cravings Likert scales and daily body confidence Likert scale as part of your study diary.

Schedule of Study Visits

You are required to fast for at least **12 hours** prior to Visit 1 and 3. (*No food or drinks except water*)

Visit 1 – Screening/Baseline (Day –45 to Day 0) **Some portions of this visit may occur virtually**
After informed consent is obtained, visit assessments will include: ▪ *Review of medical history, medications, current health status or changes in health* ▪ *Weight and height measurements. Body Mass Index (BMI) will be calculated.* ▪ *Seated resting blood pressure (BP) and heart rate (HR)* ▪ *Urine pregnancy test (If you are of childbearing potential)* ▪ *Complete Appetite, Satiety, and Cravings Likert scales and Energy Likert scales* ▪ *DEXA scan, anthropometric measurements.* ▪ *Fasted Blood samples collection* ▪ *Potential eligibility will be assessed. If you are eligible, you will be enrolled and randomized (assigned to one study group)* ▪ *Study product, study diary, 3-day food records, and all instructions will be dispensed* *This visit will take approximately 90-120 minutes to complete*
Touchpoint (Day 21 ±3 days)
Study staff will contact you to review if you have been taking the study product as instructed, address any questions you may have, and discuss any changes in your medications and/or health This phone call will take approximately 15-20 minutes to complete
Visit 2 (Day 42 + 3 days)
You will return to clinic with your completed study diaries, 3-day food records, and any unused study product in its original packaging. ▪ *Study staff will review study diary and 3-day food records* ▪ *Review any changes in medications and/or health*

- *Study staff will count the returned study product to check if you have been taking it as instructed*
- *Seated resting Blood Pressure (BP) and Heart Rate (HR) measurements*
- *Weight measurement (BMI calculation)*
- *Anthropometric measurements*
- *New study diary, 3-day food records, and study product will be dispensed*

This visit will take approximately 60-90 minutes to complete

Touchpoint (Day 63 ± 3 days)

Study staff will contact you to review if you have been taking the study product as instructed, address any questions you may have, and discuss any changes in your medications and/or health

This phone call will take approximately 15-20 minutes to complete

Visit 3 – End of Study (Day 84 + 3 days)

You will return to clinic with your completed study diaries, 3-day food records, and any unused study product in its original packaging.

- *Study staff will review study diary and 3-day Food Intake Record (FIR)*
- *Review any changes in medications and/or health*
- *Study staff will count the returned study product to check if you have been taking it as instructed*
- *Seated resting BP and HR measurements*
  - *Weight measurement (BMI calculation)*
- *Urine pregnancy test (If applicable)*
- *DEXA scan, anthropometric measurements.*
- *Fasted Blood samples collection*

This visit will take approximately 90 minutes to complete

Medications, Supplements, And Food/Drinks

If you are taking any prescribed medications, you must agree to maintain your dosing regimen during the study, unless otherwise recommended by your regular physician or other healthcare professional. 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 regular physician or other healthcare professional. 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 regular physician or other healthcare professional. 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, or currently taking any ongoing restricted substances for the study, a washout period may be required before enrollment.

Study Tests/Procedures

For some research studies, it is important that you do not learn the results of certain tests. Whether you intend it or not, sometimes learning this information may make you change your actions and behaviors in ways that could impact the outcome of the study. You will not receive the results of testing done for this study. However, information can be provided upon request from the participant once they have completed participation and the study has concluded respectively.

If the study test results show that you have a new medical condition or concern, you will be provided with these results and given recommendations for following up with your personal doctor. Sometimes these results may mean that you can no longer participate in the study. Your study doctor will let you know if this is the case.

Study Blinding

After all participants have completed the study, you will have the option to learn what study product you received.

Study Results

You will be not told about the results of the study. However, information can be provided upon request at the end of the study.

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

Risks Associated with the Study Product

It is possible that you could have problems or side effects from the study products that nobody knows about yet. There may be unknown risks with taking the study products. Potential side-effects of taking the study products may include:

- Gastrointestinal discomfort such as diarrhea, abdominal pain, constipation, and bloating.
- Liver trouble with symptoms including jaundice, stomach pain, dark urine, sweating, nausea, unusual tiredness and/or loss of appetite
- Symptoms of hypoglycemia or low-blood sugar (including feelings of anxiety, dizziness, tremor, sweating, nausea, or headache)

You should consult the study doctor if you experience fever, vomiting, bloody diarrhea, or severe abdominal pain and symptoms of digestive upset such as diarrhea lasting beyond 3-days.

Could I Have An Allergic Reaction?

It is possible for people to have allergic reactions to the study products. If you have a serious allergic reaction, you could die. 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-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.

Risks Associated with Study Procedures

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.

Since the study products are 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.

Risks related to Pregnancy

Birth Control, Pregnancy, And Breastfeeding

The effect of the study products 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 screening/enrollment 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 before screening.

Some examples of approved methods of birth control include:

- Hormonal birth control including oral medication (the pill), hormone birth control patch (Ortho Evra®), hormonal vaginal ring (NuvaRing®), hormonal injection(such as Depo-Provera®), or hormone implant (such as Nexplanon®)
- Double-barrier method (such as condom or diaphragm with spermicide).
- Intrauterine device (IUD)
- Non-heterosexual lifestyle or agree to use birth control if planning on changing to heterosexual partner(s)
- Vasectomy of partner at least 6 months before screening
- Abstinence, if this is your usual lifestyle choice, and agree to use birth control 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 removed 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.

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.

Voluntary Participation and 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.
- If you discontinue the study for whatever reason, you are expected to return all study materials, such as the study product, to the clinic.
- 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, 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 the study products 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 may provide some of the required scientific evidence for the study products in this clinical research study. Your participation in this study may support the research that is required to ensure the science behind these 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 $600.00 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). Processing times may apply before funds become available on your ClinCard.

If you are enrolled (completed visit 1 and received study product), the compensation breakdown is as follows:

- Visit 1 (Screening/Baseline)*: $150.00
- Visit 2: $200.00
- Visit 3: $250.00

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 end-of-study procedures if you consent to doing so. If you complete the early termination visit, you will be compensated $50.00.

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.
- No other form of compensation is offered.

Financial Benefits

Arrae may use information resulting from the study to develop products or processes from which it may make a profit. There are no plans to pay you or provide you with any products developed from this research. Arrae will own all products or processes that are developed using information from the study.

PRIVACY: COLLECTION, USE AND DISCLOSURE OF IDENTIFIABLE PRIVATE HEALTH INFORMATION

During your participation in this study, the study doctor and study staff will collect or create personal health information about you. The information that will be collected about you as a part of this research includes:

- Name
- Address
- Telephone number
- Birth date
- Race
- Sex
- Family medical history
- Allergies
- Medications you take (current and past)
- Results of study tests and study procedures
- Other information about your past, present, and/or future physical or mental health and/or condition from other doctors' offices, clinics, and/or hospitals that is needed for the study
- Staff at KGK Science (the contract research organization managing this study) will keep all your medical information confidential to the extent permitted by law. Disclosures required by law may include: suspected child abuse; infectious disease; expression of suicidal ideas; those situations in which research documents are ordered to be produced by a court of law; and those situations in which researchers are required to report to the appropriate authorities.
- All research data (health information, past medical history, and test results from this study) will be kept in a secured location. 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 Sterling Institutional Review Board (IRB) (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, IRB, 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 study doctor, sponsor, institution, or agents for responsibilities from mistakes. You also do not waive any of your rights as a research participant.

Your consent to collect, use and disclose IPHI will expire fifteen (15) years from the date you sign it unless you cancel it sooner. You may also take away (or withdraw) your permission for the use of your protected health information at any time. If you choose to withdraw your permission, you may contact the study doctor by phone and/or letter using the contact information on the first page of this form. The study doctor will still be able to use the health information collected about you before you withdrew your permission. Information that has already been sent to the sponsor of the study cannot be taken back.

If you withdraw your permission after you have entered the study, you cannot continue participating in the study. If you refuse to give permission or withdraw your permission, your medical care and your relationship with the health care providers at the study center will not be affected.

You have a right to see your study records; however, you will not be able to see your study records until after the study has ended.

Future Use Of Data

- Your personal information and 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.

A description of this clinical trial will be available on http://www.clinicaltrials.gov. 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.

Health Canada requires that this study be registered in a public registry for clinical trials.

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.

If you have questions regarding your rights as a research participant, or if you have questions, concerns, complaints about the research, would like information, or would like to offer input, you may contact the Sterling Institutional Review Board Regulatory Department at telephone number 1-888-636-1062 (toll free) or info@sterlingirb.com.

PARTICIPANT STATEMENT AUTHORIZATION

I have read or have the Participant Informed Consent Form and Authorization for the Collection, Use and Disclosure of Identifiable Private Health Information.

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 the 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, Sterling IRB (Research Ethics Review 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.

I know that the study product is for my use only. I will not share it with anyone, and I will store it in a safe place away from children, pets, or others for whom it is not intended.

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 know that the study product is for my use only. I will not share it with anyone, and I will store it in a safe place away from children, pets, or others for whom it is not intended.
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

_____
Signature of Participant

_____ _____AM/PM
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

_____
Signature of Person Explaining Consent

_____ _____AM/PM
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.

Participant

I voluntarily agree to participate in this study↓