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

STUDY TITLE: A randomized, triple-blind, placebo controlled, parallel clinical trial to investigate the efficacy and safety of a plant-based Celadrin on knee pain and stiffness in healthy adults with persistent knee pain

PROTOCOL NO: 25EHKGC01

STUDY DOCTOR: David Crowley, MD

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

SPONSOR: Everwell Health

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. 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 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.

KEY INFORMATION

- The purpose of the study is to evaluate the safety and effectiveness of plant-based Celadrin in adults who have ongoing knee pain.
- If you choose to participate in the study, you will be asked to attend 4 study visits, take the study product as directed, have vital signs measured, complete study assessments (6-minutes walk test (6MWT), Knee Injury and Osteoarthritis Outcome Score (KOOS)

questionnaire, and 30 seconds chair sit to stand test and complete online study diary. Your participation will last approximately 42 +3 days.

- Risks or discomfort from the study procedures include muscle and/or knee pain and stiffness from the functionality (exercise) tests. However, these are expected and typically subside naturally without persistent pain or need to intervene.
- There are no direct benefits to you from participating in this study.
- This study is not designed to diagnose, treat, or prevent any disease. Your alternative is not to take part in the study.

Background and Purpose

Knee pain and stiffness are common problems that can affect daily activities such as walking, climbing stairs, and exercising. If knee discomfort is not managed early, it may worsen over time and can sometimes develop into more serious joint conditions such as osteoarthritis. Many adults experience knee pain even without being diagnosed with osteoarthritis, and this pain can still reduce mobility, limit physical function, and negatively affect quality of life. Studies have shown that people with knee pain are much more likely to experience difficulties with lower-body movement and everyday activities compared to those without knee pain.

The study product being investigated in this research is a plant-based ingredient called Celadrin®, which is a blend of special fatty acids. These types of fatty acids have been studied for their potential to support joint comfort, improve movement, and reduce pain. Some research has shown that these ingredients may help reduce inflammation (the body's response that can cause pain and swelling) and improve joint function. Previous studies in people with joint conditions such as osteoarthritis have suggested that Celadrin may help reduce knee pain and improve movement. There is also evidence that similar fatty acid supplements may help reduce other types of muscle or joint pain.

The purpose of this study is to evaluate the efficacy and safety of plant-based Celadrin in adults who have ongoing knee pain but have not been diagnosed with osteoarthritis. The study will include adults between 35 and 75 years old, inclusive, who have experienced knee discomfort for at least three months. Researchers will assess whether the study product can help reduce knee pain and stiffness and improve overall knee comfort and function. The results of this study may help determine whether this ingredient could be a helpful option for supporting knee health in adults with persistent knee discomfort.

Study Population

This study will include approximately 80 healthy participants between 35–75 years of age, inclusive.

How Long Is the Study?

If you are eligible and enrolled in the study, your participation in this study will last approximately 45 days.

Study Design

The study design describes the plan for how the study is conducted. This is a randomized, triple-blind, placebo controlled, parallel clinical trial study.

Randomized — During Visit 1(screening/baseline), if you are eligible to participate, you will be randomly assigned by chance (like flipping a coin) to 1 of 2 study groups:

- Celadrin group
- Placebo group

You will have an equal chance of being assigned to each study 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.

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.

Placebo controlled — A placebo is an inactive substance that looks like Celadrin but has no active ingredients. It is used in research to help determine whether the study product has real effects beyond what might happen by chance or expectation.

Parallel — You stay in the same randomly assigned group for the entire study. For example, if you are assigned to the Celadrin or placebo group, you stay in that group throughout the entire study.

Study Product Information

The study product will be in soft gel form. For this study, the term “study product” refers to both the active product and placebo.

Name of study product: Celadrin

Active Ingredient	Quantity/softgel
Cetylated Fatty Acids (CFA)	325 mg CFAs

Non-active ingredients: gelatin (bovine), olive oil, purified water, glycerin, sorbitol, caramel color powder, and mixed tocopherol concentrate

Placebo

Ingredients: coconut-derived medium chain triglycerides (MCT); olive oil, gelatin (bovine), glycerin, sorbitol, purified water and caramel color powder

Directions:

- Take four soft gels of the study product daily starting on day 1 until the day before your end of study visit.
- Do not take more than 4 soft gels in a day.
- If you miss a dose, take it as soon as you remember.
- You are instructed to save all unused and remaining open study product packages and return them to the clinic to keep track of study product intake.
- You are instructed to store the study product at room temperature and not let it be exposed to direct sunlight or heat.

Rescue Medication

If you experience knee pain:

- You may take 2 regular strength acetaminophen tablets/capsules (650 mg total) if your knee hurts.
- If pain continues after 4–6 hours, you may take another 2 tablets/capsules of acetaminophen.
- You can repeat every 4–6 hours if needed, but do not take more than 9 tablets/capsules in 24 hours.
- Record every dose you take in your daily study diary.

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. Once 80 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 Specifics

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

- Complete questionnaires functionality (exercise) tests, records and diaries associated with the study and complete all study visits
- Maintain current lifestyle habits (such as diet, physical activity, medications, supplements, sleep) as much as possible throughout the study

- Refrain from taking any pain relievers during the study, except acetaminophen as a rescue medication specified by the study site
- Refrain from taking rescue medication for 48 hours prior to study 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

Urine Samples – Visits 1 and 4

- 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.

Knee Injury and Osteoarthritis Outcome Score (KOOS) Questionnaire: Visits 1, 2, 3 and 4

- You will answer questions about your knee pain, daily activities, sports, and how knee issues affect your quality of life.

6-Minute Walk Test (6MWT) - Visits 1, 2, 3 and 4

- You will walk back and forth for 6 minutes to see how far you can go and how your knees respond.

Anthropometric Measurements – Weight and Height [Visit 1], Weight [Visit 4]

- Study staff will take measurements to assess your height and weight to determine body mass index [BMI]

30-Second Chair Sit-to-Stand Test- Visits 1, 2, 3 and 4

- You will stand up and sit down from a chair as many times as you can in 30 seconds to check leg strength and mobility.

Mobility challenge pain and stiffness Likert Scale - Visits 1, 2, 3 and 4

- After the tests, you will rate how much pain or stiffness you feel in your knee.

Subject Treatment Diary

- You will complete an online daily study diary throughout the study. Questions about study product use, rescue medication taken, lifestyle habits, concomitant (current) medications any changes in medications, will be included.

Schedule of Study Visits

Visit 1 – Screening/Baseline (Day 0) **Some portions of this visit may occur virtually**
▪ Informed consent for participation in the study will be obtained ▪ Review of medical history, concomitant (current) therapy and any changes in health status ▪ Review of knee pain history, including target knee and unilateral or bilateral knee pain ▪ Vital Signs Measurements (blood pressure (BP) and heart rate (HR)) ▪ Weight and height measurements (Body Mass Index [BMI]) ▪ Urine pregnancy test for potential volunteers that are of child-bearing potential ▪ Administration of Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaire ▪ In clinic 6 min walk test (6MWT) and 30 seconds chair sit to stand exercises will be performed ▪ Mobility challenge pain and stiffness Likert Scale will be administered ▪ Potential eligibility will be assessed, and if you are eligible and still meet all study requirements, you will be randomized (assigned to a study group) and enrolled in the study ▪ Dispense study product and instruct participants on use ▪ Dispense subject treatment diary and instruct participants on completion This visit will take approximately 90-120 minutes/hours to complete
Visit 2 – (Day 7 + 3 days)
▪ You will return to the clinic for **visit 2 assessments** with unused study product and completed subject treatment diary ▪ Review of subject treatment dairy, concomitant (current) therapies including rescue medication and any changes in health status ▪ Vital Signs Blood Pressure (BP) and Heart Rate (HR) Measurements ▪ Clinic staff will calculate compliance to study product intake by counting the returned unused study product to confirm if you have been taking the study product as directed ▪ Administration of KOOS questionnaire ▪ In clinic 6 min walk test (6MWT) and 30 sec chair sit to stand exercises will be performed ▪ Mobility challenge pain and stiffness Likert Scale will be administered ▪ Dispense new study diary and instruct participant on completion ▪ Dispense new study product and instruct participants on use This visit will take approximately 60-90 minutes to complete
Visit 3 (Day 21 + 3 days)
▪ You will return to the clinic for **visit 3 assessments** with unused study product and completed subject treatment diary ▪ Review of subject treatment dairy, concomitant therapies (current) including rescue medications and any changes in health status ▪ Clinic staff will calculate compliance to study product intake by counting the returned unused study product to confirm if you have been taking the study product as directed ▪ Vital signs Blood Pressure (BP) and Heart Rate (HR) Measurements ▪ Administration of KOOS questionnaire

▪ In clinic 6 min walk test (6MWT) and 30 seconds chair sit to stand exercises will be performed ▪ Mobility challenge pain and stiffness Likert Scale will be administered ▪ Dispense new study diary and instruct participants on completion ▪ Dispense new study product and instruct participants on use This visit will take approximately 60-90 minutes to complete
Visit 4 – End of study (42 + 3 days)
▪ You will return to the clinic for **visit 4 assessments** with unused study product and completed subject treatment diary ▪ Review of subject treatment diary, concomitant (current) therapy including rescue medication and any changes in health status ▪ Vital signs (Blood Pressure (BP) and Heart Rate (HR)) Measurements ▪ Weight measurements ▪ Urine pregnancy test for volunteers that are of child-bearing potential ▪ Administration of KOOS questionnaire ▪ In clinic 6 min walk test (6MWT) and 30 seconds chair sit to stand exercises will be performed ▪ Mobility challenge pain and stiffness Likert scale will be administered ▪ Clinic staff will calculate compliance to study product intake by counting the returned unused study product to confirm if you have been taking the study product as directed This visit will take approximately 60-90 minutes to complete

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.

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 once you 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 not be told about the results of the study. However, information can be provided upon request from the participant 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 Celadrin that nobody knows about yet. There may be unknown risks with taking the study product.

Celadrin is generally well tolerated; however, mild gastrointestinal symptoms, including nausea, diarrhea, bloating, constipation, indigestion, or other digestive discomfort, may occur.

Risks Associated with the Study Procedures

You might feel soreness and pain in the knees due to the in exercises done in clinic. These are expected and typically subside naturally without persistent pain or need to intervene.

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.

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.

Risks Related to Pregnancy

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 **at Visit 1 and visit 4 a negative 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), vaginal ring (NuvaRing), injection (such as Depo-Provera, Lunelle), or hormone implant (such as Norplant System)
- Double-barrier method
- Intrauterine devices (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 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 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 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 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 $500.00 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): $100.00
- Visit 2: $120.00
- Visit 3: $130.00
- Visit 4: $150.00

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 visit 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

Everwell Health 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. Everwell Health 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 or server. Forms on which your information is entered will not contain your name (except for the 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 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.
- 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 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 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, 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 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

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 the pages of the information presented in it.

Participant

I voluntarily agree to participate in this study