PARTICIPANT INFORMED CONSENT FORM

STUDY TITLE: An open-label, dose-escalation clinical trial to assess the pharmacokinetic profile of propylene glycol (PG) in healthy adults following PG exposure

PROTOCOL NO: 26ABAKC01

STUDY DOCTOR: David Crowley, MD

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SPONSOR: American Beverage Association

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

Things you should know:

- The purpose of this study is to better understand how drinking beverages that contain Propylene Glycol (PG) affect the amount of PG in the bloodstream.
- If you choose to participate, you will be asked to attend 7 study visits, take the study product as directed, provide blood and urine samples, undergo vital signs including body temperature, heart rate, blood pressure and oxygen levels as well as anthropometrics measurements (including weight and height), and complete an online study diary and food records. Your participation will take approximately 12 days.

- Potential side effects of taking the study product may include increased acid levels and body fluid imbalance.
- Risks or discomforts from this research may include a small chance of minor bruising or, rarely, infection at the needle site from blood draw; this risk is minimized as all blood samples are collected by qualified healthcare professionals using standard, safe blood collection procedures.
- There is no direct benefit to you from participating in this study.
- This study is not designed to diagnose, treat, or prevent any disease. Your alternative is to not take part in the study.

Background and Purpose

Propylene glycol (often called “PG”) is a common ingredient found in many everyday products, including foods, drinks, and some medications. It helps keep products moist, improves texture, and helps ingredients mix together. Health authorities such as the Food and Drug Administration and the European Food Safety Authority have approved its use because it has generally been considered safe at typical levels.

When you consume PG, your body absorbs it and breaks it down into substances that are naturally found in the body. However, when people are exposed to higher amounts, the body may process it more slowly, which can lead to changes in the blood. Most of the available research on how PG behaves in the body has been done in people who are ill, rather than in healthy individuals consuming it through their diet. **The reactions seen in ill patients were a build-up of acid levels and body fluid imbalance.** The purpose of this study is to better understand how drinking beverages that contain Propylene Glycol (PG) affects the amount of PG in bloodstream. In this study, you will be asked to drink one, two, or three bottles (12 oz each) of a beverage that contains a specific amount of PG. Each participant will try different amounts in separate visits so researchers can compare how the body responds. Participants in this study will consume one, two, or three bottles of a 12 oz beverage containing PG at 3000 ppm concentration (that is, 1065 mg of PG per 12oz) on three separate dosing days during the study. This results in a PG intake of approximately 15 mg/kg body weight (bw)/day, 30 mg/kg bw/day, 46 mg/kg bw/day (considering an average weight of 70 kg for an adult) when consuming one bottle, two bottles, and three bottles of the study beverage, respectively. Administration of two or three bottles of a 12 oz PG-containing beverage in this study would lead to a PG dose higher than the recommended total allowance of 25 mg/kg bw/day.

Study Population

This study will include approximately 30 healthy males and females aged 18 years and older.

How Long Is the Study?

If eligible and enrolled in the study, your participation in this study will last approximately 12 days.

Study Design

The study design describes the plan for how the study is conducted. This is an open-label, dose-escalation clinical trial to assess the pharmacokinetic profile of propylene glycol (PG) in healthy adults following PG exposure

Open-label — Everyone involved, including you, the study staff, and the researchers analyzing the data will know which study product you are receiving. All participants will receive the same study product.

Study Product Information

The study product will be in a liquid form

Name of study product:

12 oz PG-containing beverage

Ingredient	Quantity
Food-Grade Propylene Glycol	3000 ppm

Other ingredients: purified water

Directions:

You will consume 1 bottle, 2 bottles, and 3 bottles of a PG-containing beverage (in 12 oz bottle format) with standardized meals in the presence of study staff over the course of the study visit dosing day.

You will consume the beverage and standardized meal within 15 minutes.

The only beverage you are allowed during the visit, other than the study product, will be water.

Water will be provided as needed at visit 2, and water consumption during future visits will be matched as much as possible to the amount of water consumed at visit 2.

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 30 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:

- Consume the study product and the standardized meal
- Refrain from consuming alcohol and engaging in vigorous physical activity for 24-hours prior to dosing day (in other words, 24- hours before day 1 of each study period which corresponds to visits 2, 4, and 6) and day 2 of each study period.
- Complete diaries, food records, and complete all clinic visits.
- Maintain current lifestyle habits (such as diet, physical activity, medications, supplements, and sleep) as much as possible throughout the study.

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 – Screening (Visit 1), visits 2, 3, 4, 5, 6 and at the end of study visit (visit 7) or early termination visit.

- The total blood volume collection will be approximately 925 mL (approximately 61 tablespoons), over the period from screening to the end of the study (approximately 52 days). At any study visit, blood volume collected is not expected to exceed 365 mL (approximately 24 tablespoons). Additional blood samples may be collected during the study, if necessary, such as in cases of abnormal test results or processing errors, or to conduct or repeat laboratory tests.
- At visits 2, 4 and 6, an intravenous catheter will be placed to help facilitate multiple blood draws. The catheter will be flushed with saline to keep it clear and working properly throughout the visits. Conventional phlebotomy/venipuncture (blood draw from a vein using a needle) will also be used in this study, such as at visits 1, 3, 5, and 7, and may also be used during visits 2,4 and 6 if the catheter is not working properly.

All samples will be sent to an external laboratory for analysis at the end of each day and/or as scheduled shipment at the end of the study. 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, the 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 – Visit 1 (screening), visit 2 (baseline), visit 7 (end of study) 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.

Anthropometric Measurements – Visit 1 [Height and Weight Measurements], visit 2, 4, 6 [Weight Measurements]

- Study staff will take measurements to assess your height and weight at screening (visit 1) to calculate Body Mass Index [BMI] calculation. Clinic staff will take measurements of weight only at study visits 2, 4 and 6.

Food Records

- You will report your food and drink intake in a 3-day food record which you will complete prior to visits 2, 4, 6. 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, concomitant medications, and any changes in health status will be included.

Schedule of Study Visits

You are required to fast for at least 8 hours prior to study visit 2 and study visit 7. You are also asked to refrain from vigorous physical activity and alcohol consumption 24 hours prior to study visit 2 and study visit 7.

Visit 1 – Screening (Day -45 to Day -1)
After obtaining the Informed consent, the screening assessments with include: ▪ Review of your medical history, current medications, and current health status ▪ Potential eligibility will be assessed ▪ Urine pregnancy test for potential participants that are of child-bearing potential (if applicable) ▪ Weight and Height Measurements ((Body Mass Index [BMI]) calculations) ▪ Seated resting Blood Pressure (BP), Heart Rate (HR), Body Temperature and Oxygen measurements ▪ Blood sample collection ▪ Dispense 3-day food records and instruct you on completion This visit will take approximately 90 minutes to complete. The next visit will be scheduled for potentially eligible participants.

Visits 2, 4, 6 (Day 1)

- You will return to the clinic fasted for at least 8-hours for Day 1 assessment
- You will return to the clinic with completed 3-day food records
- Urine pregnancy test for participants that are of child-bearing potential (visit 2)
- Review of current medications and any changes in health status
- Potential eligibility will be assessed (visit 2)
- Vital sign (BP, HR, Body Temperature) and Oxygen Measurements
- Weight Measurements (BMI calculation) (visit 2)
- Clinic staff will review 3-day food records
- Clinic staff will review study diary (visits 4, 6)
- Blood sample collection **before** study product and standardized meal administration
- You will be instructed by clinic staff to consume 1 bottle, 2 bottles, and 3 bottles of PG-containing beverage in bottle format with standardized meals
- PG-containing beverage and standardized meal administration (T=0)
- Blood sample collection **after** study product and standardized meal administration (T= 0.5-hour, 1- hour, 1.5 hours, 2 hours, 4 hours, 5 hours, 6 hours, 8 hours, 9 hours, 12 hours)
- Dispense study diary and instruct you on completion

Clinic staff will administer PG-containing beverage and standardized meal at T=4 hours (visits 4, 6) and T=8 hours (Visit 6).

You will be allowed to consume the next higher dose of the study product based on the review of your health status and safety blood test results.

Visits 4 and 6 will be scheduled after a minimum 3-day washout period.

This visit will take approximately 13 hours to complete.

Visits 3, 5, 7 (Day 2)

- You will return to the clinic fasted for at least 8-hours for Day 2 assessments
- You will return to the clinic with completed study diary
- Clinic staff will review the study diary
- Clinic staff will dispense new 3-day food records (visits 3, 5) and instruct you on completion
- Clinic staff will dispense new study diary (visits 3, 5) and instruct you on completion
- Clinic staff will review concomitant therapies and any changes in health status
- Urine pregnancy test (visit 7)
- Vital Signs (BP, HR, Body Temperature) and Oxygen Measurements
- Blood sample collection (T=24 hours)

This visit will take approximately 30 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 may request the results of the study once the study is complete.

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 Results

You may request the results of the study once the study is complete.

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

Potential side effects from taking the study product include increased acid levels and body fluid imbalance. Some marketed beverages contain PG amounts being evaluated in this study, these beverages have been in the marketplace for decade(s). It is possible that you could have problems or side effects from the study product that nobody knows about yet.

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.

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.

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 urine pregnancy test on study visits 1, 2 and 7 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 birth control including oral medication (the pill), an intrauterine device (IUD), a hormonal implant (such as Nexplanon®), a hormonal injection (such as Depo-Provera®), a hormonal patch (Ortho Evra®), a hormonal vaginal ring (NuvaRing®) Double-barrier method method (such as condom or diaphragm with spermicide)
- 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 prior to 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 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.

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.
- If you discontinue the study for whatever reason, you are expected to return all study materials 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 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 for a total of $1500.00 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, the compensation breakdown is as follows:

- Visit 1 (Screening): $0.00
- Visit 2: $100.00
- Visit 3: $150.00
- Visit 4: $250.00
- Visit 5: $300.00
- Visit 6: $350.00
- Visit 7: $350.00

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 final visit evaluation 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.

Financial Benefit

American Beverage Association (ABA) 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. **American Beverage Association (ABA)** will own all products or processes that are developed using information from this 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 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 - Sterling 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, IEB, 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 withdraw 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 them or identify you.

Study doctors, including study doctors from collaborating institutions, can request this data for new research. Samples and 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 or samples 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.

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 AND 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 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.

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

_____
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 the pages of the information presented in it.

Participant

I voluntarily agree to participate in this study