PARTICIPANT INFORMED CONSENT FORM

STUDY TITLE: A randomized, double-blind, placebo-controlled, parallel clinical trial to investigate the safety and efficacy of Bloat on postprandial bloating and its effects over time in healthy women

PROTOCOL NO: 25ARCCB01

STUDY DOCTOR: David Crowley, MD

STUDY SITE: KGK Science Inc.
275 Dundas Street, Tower A, Suite G02
London, ON N6B 3L1

TELEPHONE: 519-438-9374 (24 hours)

SPONSOR: Arrae

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 may 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.

Use the phone number listed on the first page of this document to contact study staff.

KEY INFORMATION

Things you should know:

- The purpose of the study is to investigate the safety and how well Bloat works on post-meal bloating in healthy women.
- If you choose to participate, you will be asked to attend two study visits where you will have vital signs and body measurements taken and complete questionnaires, then you will take the study product at home daily and complete a study diary for 55 days. Your participation will last approximately 56 days.

- Risks or discomforts from this research include nausea, vomiting, digestive upset/discomfort, cough, loss of appetite, drowsiness, restlessness, and nervousness.
- 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 not to take part in the study.

Background and Purpose

Stomach bloating after a meal is a common symptom that includes a feeling of fullness, gas, or pressure, along with visible enlargement of the stomach. Persistent stomach discomfort can make everyday tasks difficult and lead to a decreased quality of life. It can have many causes, some of which are not fully understood. Because bloating can vary from person to person, treatment options are also varied—and currently limited. This creates an opportunity to explore natural approaches, such as complementary and alternative medicines.

The product used in this study, called **Bloat**, is a blend of ginger root extract, bromelain, peppermint leaf extract, dandelion root extract, lemon balm herb top extract, and slippery elm inner bark extract. Early studies suggest that these herbs—when studied alone or combined with other digestive enzymes—may help support digestive comfort.

The purpose of this study is to investigate the safety and efficacy of Bloat (how well it works) on post-meal bloating in healthy women.

Study Population

This study will include 100 healthy females aged 18 to 65 years old, inclusive.

How Long Is the Study?

If eligible and enrolled in the study, your participation will last approximately 56 days.

Study Design

This is a randomized, double-blind, placebo controlled, parallel clinical trial study.

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

- **Bloat** 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.

Any reference to the term “study product**”** refers to what you will take as part of your participation. This may be the active product (**Bloat**) or placebo.

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 active product but has no active ingredients. It is used in research to help determine whether the product being studied 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 **Bloat** group or placebo group, you stay in that group throughout the entire study.

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 criteria and do not meet any 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 100 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.
- If you voluntarily agree to participate in this study, you must be willing to:
  - Agree to maintain your current lifestyle habits (diet, physical activity, medications, supplements, and sleep) throughout the study.
  - Consume a standardized meal (two slices of a large cheese pizza) during your Screening/Baseline visit.
  - Complete all study assessments including questionnaires and an online daily study diary.
- You should not participate in this study if:
  - Someone who lives with you in the same household is currently participating in this study.
  - Currently have or have a history of any significant diseases of the GI tract or digestive disorders or you take any medications that slow down bowel movements (such as opioids or anti-diarrhea medicine like loperamide)

What Will Happen During This Study?

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

Assessments and Procedures

Body Measurements

Study staff will take measurements of both your height and weight at the screening/baseline (Visit 1), weight measurement only at Visit 2 and waist circumference only at Visit 1 (before the standardized meal, after the standardized meal and at 60 minutes after study product administration).

Urine Samples – Visit 1 and Visit 2.

Individuals of child-bearing potential will be required to take a urine pregnancy test. You will be provided with a collection container and instructed on how to provide the sample. The urine pregnancy test will be performed at the study site.

Standardized Meal – Visit 1

You will be provided a standardized meal to eat during your Visit 1 (screening/baseline), consisting of two slices of a large cheese pizza. You will need to eat the entire standardized meal to continue participating in the study.

Gas, bloating, and abdominal discomfort/distension numeric rating Scales – Visit 1 and weekly

These scales will be used during your Visit 1 (screening/baseline) to measure gas and bloating before and after eating the standardized meal, and after taking the study product. You will also complete the scales in your diaries once a week.

Patient-Reported Outcomes Measurement Information System Gastrointestinal Symptoms Scales (PROMIS-GI) – Visit 1, Day 28, Visit 2

You will be asked to complete questionnaires about gastrointestinal (GI) symptoms, including gas and bloating (PROMIS-GI Gas and Bloating Scale), reflux (PROMIS-GI Reflux Scale), and belly pain (PROMIS-GI Belly Pain Scale).

Study Diary

You will complete a daily study diary throughout the study. Questions about study product use, lifestyle habits, menstruation, medications, and changes in health will be included. Gas and Bloating Likert Scales will be included in your diaries once a week.

Schedule of Study Visits

You will be required to fast (only water, no food) for 8-hours before your baseline/screening visit.

Study procedures will take place as follows:

Visit 1 – Screening/Baseline (Day -45 to Day 1)
▪ Informed consent is obtained ▪ Review of medical history, medications, current health status or changes in health ▪ Urine pregnancy test (if you are of childbearing potential) ▪ Seated blood pressure (BP) and heart rate (HR) ▪ Weight and height measurements. Body Mass Index (BMI) will be calculated ▪ Review of your history of bloating and distention ▪ Potential eligibility will be assessed ▪ Completion of questionnaires before receiving the study product: PROMIS-GI Gas and Bloating Scale, PROMIS-GI Reflux Scale, PROMIS-GI Belly Pain Scale, Gas, Bloating, and Abdominal Discomfort/Distension numeric rating scales, and waist circumference measurement ▪ Consumption of a standardized meal ▪ 30 minutes after eating, you will complete the Gas, Bloating, and Abdominal Discomfort/Distension numeric rating scales again ▪ If you are eligible, you will be randomized (assigned to one study group) and will take the assigned study product (**Bloat** or placebo), and waist circumference measurement ▪ You will complete the Gas, Bloating, and Abdominal Discomfort/Distension numeric rating scales at 30 minutes, 60 minutes (along with measurement of waist circumference), and 120 minutes after taking the study product. ▪ The study product and diaries will be provided to you, along with instructions to take at home. This visit will take approximately 3 hours to complete.
Touchpoints Day 14 (± 3 days) and Day 42 (± 3 days)
▪ Study staff will contact you to check if you have been following study instructions (including taking the study product as directed), answer any questions you may have and review any changes in your health or medications. Each visit will take approximately 15 minutes to complete.
Day 28 (+ 3 days)
▪ Study staff will review your diaries to check if you have been following study instructions (including taking the study product as directed) and review any changes in your lifestyle habits, health or medications. ▪ You will complete the PROMIS-GI Gas and Bloating scale, PROMIS-GI Reflux Scale, and PROMIS-GI Belly Pain Scale in your diary This visit will take approximately 30 minutes to complete.
Visit 2 - End of Study (Day 56 + 3 days)
You will return to the study site with your completed study diaries and any unused study product in its original packages.

- You will be asked to return and review your completed study diaries
- Study staff will review any changes in health or medications
- Urine pregnancy test (if you are of childbearing potential)
- Seated BP and HR
- Weight measurement. BMI will be calculated
- You will complete questionnaires: PROMIS-GI Gas and Bloating Scale, PROMIS-GI Reflux Scale, PROMIS-GI Belly Pain Scale

This visit will take approximately 1 hour to complete.

Study Product Information

The study product will be in capsule form.

Bloat:

Medicinal Ingredient	Quantity (per capsule)
Ginger Root Extract	110 mg
Dandelion Root Extract	108 mg
Lemon Balm Herb Top Extract	108 mg
Peppermint Leaf Extract	108 mg
Bromelain	3888000.0 FCC PU
Slippery Elm Inner Bark Extract	108 mg

mg: Milligram FCC PU: Food Chemical Codex Papain Unit

Non-active ingredients: Hypromellose capsule

Placebo:

Ingredients: White rice flour, caramel brown E 270, Hypromellose capsule.

Directions:

At the study site:

- You will be instructed to take one dose (2 capsules) 30 minutes after eating the standardized meal provided with water during the screening/baseline clinic visit (Day 1).

At home:

- You will take one dose (2 capsules) daily with water, after dinner, for a total of 55 days.

- You should take the study product at least two hours before or two hours after regular medication
- If you miss one dose, take the missed dose when you remember on the same day or if it is not until the next day.
- Do not take more than one dose (2 capsules) daily. Do not take more than one dose per day to compensate for a missed dose.
- Store the study product at room temperature and do not expose to direct sunlight or heat and keep out of the reach of children and pets.
- You will save all unused and open study product packages and return it to the clinic at your last study visit.

Alternative Treatments

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

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, you may request information once you have completed participation, and 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 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, you may request information.

Additional Safeguards

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

Risks To You

It is possible that you could have problems or side effects from the study products that nobody knows about yet. There may be unknown risks with taking the study product. Potential side-effects of taking the study products may include, but are not limited to:

- Nausea and vomiting associated with motion sickness and/or seasickness
- Digestive upset/discomfort
- Cough, persist or worsen
- Loss of appetite
- Drowsiness. You are advised to proceed with caution when driving or using machinery due to potential side effects
- Restlessness and/or nervousness
- Mild digestive disturbance or indigestion

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, 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 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.

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. If your healthcare provider recommends any medication or dose changes, notify the study staff immediately.

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 you stop your regular medications, 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.

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.

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.

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 prior to screening.

Some examples of approved methods of birth control include:

- Hormonal birth control including oral birth control (the pill), hormone birth control patch (Ortho Evra®), hormonal vaginal ring (NuvaRing®), hormonal injectable (such as Depo-Provera®), or hormone implant (such as Nexplanon®)

- Double-barrier 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 by 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. There is also risk that the PDF copy of the consent cannot 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, such as the study product, to the study site.
- You may be asked to undergo some final visit procedures. These may include returning to the study site to complete any end-of-study assessments or questionnaires.
- If the study doctor or study staff finds out any related information that may 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 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
- Inappropriate enrollment (did not meet eligibility criteria)

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 product and examinations 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.

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

- Visit 1 (Screening/Baseline): $120.00
- Day 28: $180.00
- Visit 2: $200.00

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 tests and visit procedures if you consent to doing so. If you complete the early termination visit, you will be compensated $50.00.

If you are present at the study site for your first visit (screening/baseline) but are deemed not eligible to continue in the study by study staff, you may be eligible for $50.00 compensation for your time.

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 commercial products or other valuable discoveries result from the research using your information, these products and discoveries may be owned, patented, licensed or otherwise developed for commercial sale by the sponsor, other researchers, or companies. If this should occur, you will not receive any payment or have any ownership or rights from any discoveries that may result from such research.

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.

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 the Institutional Review 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.
- 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.

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 by 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 the Participant Informed Consent Form. 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, Institutional 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 understand that I am expected to keep a copy of this signed and dated consent form for my records.

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