PARTICIPANT INFORMATION AND CONSENT FORM

Sponsor/Study Title:	Nexira / "A randomized, triple-blind, placebo controlled, parallel clinical trial to investigate the efficacy of Acacia fiber on gastrointestinal health and microbiota composition in healthy adults with occasional constipation"
Protocol Number:	25NXCRR01
Principal Investigator: ***(Study Doctor)***	David Crowley, MD
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Making an Informed Decision

You are invited to participate in a clinical research study. Participation in this study is strictly voluntary. To make an informed decision about participating in this study, it is important that you understand the potential risks and benefits of the study. This process, known as informed consent, ensures you have all the information needed to decide. 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 have access to this form and can review it at your leisure before making a decision.

You should not sign this form until you fully understand the information provided, feel comfortable with your decision to participate, and have had all your questions about the study answered to your satisfaction. You will be provided with a signed copy of this form and are expected to keep it for your record. Once consent has been obtained, the study assessments will proceed.

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

Background and Purpose

Constipation is a common digestive condition that may involve infrequent bowel movements, difficulty passing stools, abdominal discomfort, and bloating. While some individuals meet medical criteria for chronic (lasting condition) constipation, many people experience occasional constipation, which is characterized by intermittent or bothersome changes in bowel habits without serious medical features. Even when symptoms are not persistent, constipation can negatively affect daily comfort and quality of life. Common treatments include over-the-counter products such as laxatives and stool softeners, as well as increased dietary fiber intake; however, many individuals report incomplete symptom relief or unwanted side effects, and most adults do not consume sufficient fiber through diet alone.

Certain dietary fibers have prebiotic properties, meaning they may support the growth or activity of beneficial gut bacteria and contribute to digestive health. The investigational product used in this study, Inavea™ Pure Acacia, is a soluble fiber derived from the sap of the Acacia tree. Previous clinical studies have suggested that acacia fiber supplementation may support bowel regularity and improve certain digestive symptoms, including stool frequency and bloating. However, additional research is needed to better understand its effects, particularly in adults experiencing occasional constipation.

Study Population

This study will include approximately 105 healthy males and females between 30-60 years of age.

How Long Is the Study?

If eligible and enrolled in the study, your participation in this study will last approximately 56 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 #2, if you are eligible to participate, you will be randomly assigned by chance (like flipping a coin) to 1 of 3 study groups:

- Low-dose Acacia fiber group (5g/day)
- High-dose Acacia fiber group (10g/day)
- Placebo group

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

Any reference to the term “study product” refers to what you will take as part of your participation. This may be the Acacia fiber or placebo.

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 the Acacia fiber but has no active ingredients. It is used in research to help determine whether the Acacia fiber 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 study product 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 and exclusion criteria for this study.
- By signing this consent form, you are not guaranteed to be enrolled in the study. Your participation depends on meeting the study's specific eligibility criteria, which will be determined through a series of questions and assessments.

- This study uses competitive enrollment. This means that once 105 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:

- Agree to maintain your current dietary habits and lifestyle habits (diet, physical activity, medications, and sleep) as much as possible throughout the study
- Be willing to complete questionnaires, records, and diaries associated with the study, as well as complete all clinic visits
- Be willing to collect fecal (stool) samples
- Fast at least 12 hours (no food or drinks except water) prior to scheduled study visits 2 and 4

What Will Happen During This Study?

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

Assessments and Procedures

Blood Samples – Visits 1, 2 and 4

- The total blood volume collection will be approximately 165 mL (approximately 11 tablespoons), over the period from screening (Visit 1) to the end of the study (Visit 4) (approximately 101 days). At any study visit, blood volume collected is not expected to exceed 78 mL (approximately 5 tablespoons). Additional blood samples may be collected during the study, if necessary, such as in cases of abnormal test results or processing errors, to conduct or repeat laboratory tests.

Urine Samples – Visits 1, 2 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.

Stool Samples – Visits 2, 3 and 4

- Stool samples will be collected at visits 2, 3 and 4 using the dispensed collection kit. You will be given a stool collection kit containing the materials required to collect your sample. You are instructed to collect your sample within 2-days prior to your scheduled clinic visit.

Food Frequency Questionnaire – Visit 1

- At screening visit, you will complete a questionnaire to determine your average intake of fiber. The questionnaire includes questions of common sources of fruit and vegetables. You are instructed to rate your frequency of consuming these foods using a scale of 0 to 5.

Food Records

- You will complete these 3-day food records (3DFR) on two weekdays and one weekend day of the run-in period (period prior to baseline or day 0 of 56 days of participation). If you enroll in the study

at Visit 2 you will complete additional 3 day food records in the week leading up to your Visit 3 and Visit 4. You will complete a total of three 3-day food records over the course of the study.

Bowel Habits Dairy (BHD) and Bristol stool scale (BSS)

- BHD evaluates each bowel movement with questions pertaining to number of bowel movements, sense of complete evacuation, use of medications (such as laxatives) and the start and end date of menstrual cycle for female participants. You are instructed to complete this daily diary during the run-in and throughout the study period.

Bristol Stool Scale (BSS)

- The BSS is a 7-item stool description and image scale that assesses the shape and consistency of stools. You will complete these daily during the run-in and throughout the study periods.

Study Diary

- You will complete an online study diary daily during the two week run-in period and throughout the study. They will include the Bowel Habit Diary (BHD) and Bristol Stool Scale (BSS) as well as questions pertaining to study product use, physical activity, intake of liquids, mensuration and any changes in health, and concomitant therapies.

Patient Assessment of Constipation Quality of Life (PAC-QoL) – Visits 2, 3 and 4

- This questionnaire asks about how constipation may have affected your daily life over the past two weeks, including physical and psychosocial discomfort, worries, and satisfaction.

Modified Gastrointestinal Symptoms Rating Scale (GSRS) Questionnaire – Visits 2, 3 and 4

- This questionnaire asks about common stomach and bowel symptoms, such as abdominal pain, reflux, diarrhea, indigestion, and constipation, and how severe these symptoms feel to you.

Sleep and Stress Likert scale – Visits 2, 3 and 4

- This short questionnaire asks you to rate how satisfied you feel with your sleep and your overall mood using a simple rating scale. You are instructed to indicate your response on the scale from 0 to 3 for the following statement: “overall, I am satisfied with my sleep”.

Schedule of Study Visits

You are required to fast for at least 12 hours (no food or drinks except water) prior to your scheduled study visits 2 and 4.

Visit 1 – (Screening, Day –45 to Day –15)
• Informed consent is obtained • Review of medical history, medications, current health status and any changes in health • Potential eligibility will be assessed • Urine pregnancy test for potential participants that are of childbearing potential (if applicable) • Seated resting Blood Pressure (BP) and Heart Rate (HR) measurements • Weight and height measurements (BMI calculations) • Blood samples collection • Food Frequency Questionnaire will be provided • Fecal kit and instructions on participant on use will be provided

- Daily study diary, including Bowel Habit Diary (BHD) and Bristol Stool Scale (BSS), and instructions for participant on completion will be provided
- *The next visit will be scheduled for eligible participants after a 2-week run-in period*

Visit 2 – (Baseline, Day 0)

- Return to the clinic fasted for at least 12-hours for baseline assessments
- Return to clinic with completed study diary including BHD and BSS, food records and fecal sample
- Review medications, therapies, and current health status
- Urine pregnancy test for potential volunteers that are of childbearing potential (if applicable)
- Seated resting BP and HR measurements
- Weight measurements (BMI calculation)
- Administration of the Patient Assessment of Constipation Qualify of Life (PAC-QoL), Gastrointestinal Symptoms Rating scale (GSRS) questionnaire, and Sleep and Stress Likert Scale
- Blood sample collection
- If you still meet all study requirements and are eligible, you will be randomized (assigned to a study group).
- Study product and instructions for participant on use will be provided
- Stool kits and instructions for participant on use will be provided
- Study diary, including BHD and BSS, and food records and instructions for participant on completion will be provided

Visit 3 – Day 28 (± 3)

- Return to the clinic with unused study product
- Your compliance to the study product will be calculated (see if you are taking the study product as instructed) based on the unused study product, completed study diaries (including BHD and BSS), food record and fecal sample
- Review study diary, including BHD and BSS, food records, medications, therapies, and any changes in health status
- Seated resting BP and Heart Rate HR measurements
- Weight measurements (BMI calculation)
- Administration of the Patient Assessment of Constipation Qualify of Life (PAC-QoL), Gastrointestinal Symptoms Rating scale (GSRS) questionnaire, and Sleep and Stress Likert Scale
- Study product and instructions for participant on use will be provided
- Stool kits and instructions for participant on use will be provided
- Study diary, including BHD and BSS, and food records and instructions for participant on completion will be provided

Visit 4 – (End of Study, Day 56 (± 3))

- Return to the clinic fasted for at least 12 hours for end of study assessment
- Return to the clinic with unused study product
- Your compliance to the study product will be calculated (see if you are taking the study product as instructed) based on the unused study product, completed study diaries (including BHD and BSS), food records and stool sample

- Review study diary including BHD and BSS, food records, medications, therapies, and changes in health status
- Urine pregnancy test for participants that are of childbearing potential (if applicable)
- Seated resting BP and HR measurements
- Weight measurements (BMI calculation)
- Administration of the Patient Assessment of Constipation Qualify of Life (PAC-QoL), Gastrointestinal Symptoms Rating scale (GSRS) questionnaires and Sleep and Stress Likert scale
- Blood Sample collection
- Your occasional constipation will be evaluated.

Medications, Supplements, and Food/Drinks

Prescribed Medications

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

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

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

Washout Period – A specific amount of time recommended by the study doctor to allow restricted substances (such as medications, supplements, foods or drinks) to clear from the body before beginning the study. If you have recently taken or stopped any restricted substances or participated in activities that conflict with the study, a washout period may be required before enrollment.

Birth Control, Pregnancy, and Breastfeeding

The effect of the study product on pregnancy and breast milk is not known. You must not participate if you are pregnant, breastfeeding or planning to become pregnant during the study.

Individuals able to become pregnant (not post-menopausal, have had a menstrual period in the past 1 year, or have not had any of the following surgeries: hysterectomy, bilateral oophorectomy, complete endometrial ablation, or bilateral tubal ligation) must have a negative Visit 1, 2 and 4 urine pregnancy test and agree to use a medically approved method of birth control for the duration of the study. If you are using hormonal birth control, you must have been using it for at least 3 months prior to screening.

Some examples of approved methods of birth control include:

- Hormonal contraceptives including oral contraceptives, hormone birth control patch, vaginal contraceptive ring, injectable contraceptives, or hormone implant
- Double-barrier method
- Intrauterine devices (IUD)
- Non-heterosexual lifestyle or agree to use contraception if planning on changing to heterosexual partner(s)
- Vasectomy of partner at least 6 months prior to screening
- Abstinence and agree to use contraception if planning on becoming sexually active during the study

If you become pregnant during the study, you must stop taking the study product immediately and contact the study staff. You will be withdrawn from the study and the study doctor will follow up with you until the child's birth, collect information about your pregnancy, its outcome, and the health of your child.

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

Study Product Information

The study product will be in powder in sachet form.

Name of study product: Inavea™ Pure Acacia

Medicinal Ingredient	Quantity/Daily Dose
100% gum acacia	5 or 10 g

Placebo:

Ingredients: Dextrose

Directions:

- You will start taking the study product on Day 1 (the day after your baseline visit).
- You will take 1 sachet per day on Days 1–4.
- You will take 2 sachets per day from Day 5 until the day prior to your end of study visit (Day 55) .
- You will not take the study product on Day 56.
- If a dose is missed or you forget to increase your dose at day 5, you are required to take the dose or remaining portion of the dose when you remember
- You will not exceed 2 sachets per day. When taking 2 sachets in one day, you will try to space doses at least 4 hours apart.
- You will empty the full contents of each sachet into a food or drink you regularly consume (e.g., yogurt, juice, smoothie). You are instructed not to introduce new food/beverage vehicles that you previously consumed.

- You will save all used, unused, and opened sachets and return all sachets to the study site at Visit 3 and Visit 4.

Alternative Treatments

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

Additional Safeguards

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

Risks To You

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

- Increased stool amount
- Nausea
- Abdominal pain
- Digestive discomfort

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, and whether you think these problems are related to the study products or not.

Potential Risks From E-Consent

You may receive a link via email/text message to download a PDF copy of this signed consent form. There may be risks of loss of privacy and confidentiality if the PDF copy of this consent form is viewed and/or stored on a personal electronic device (PED), especially if that PED is shared with other users or is lost, hacked, or subject to a search warrant or subpoena. Also, the PDF copy of the consent may not be able to be permanently removed from a PED.

Withdrawal From the Study

- Your participation in this research is strictly voluntary. You have the right to choose not to be in the study or leave at any time, for any reason, without affecting your relationship with the study doctor or study staff and without penalty or loss of benefits to which you are otherwise entitled.
- 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 will provide some of the required scientific evidence for the study products in this clinical research study. Your participation in this study supports the research that is required to ensure the science behind the study products.

Costs To You

- All the tests, study products, examinations, and medical care required as part of this study are provided at no cost to you, the public health plan, or your private medical insurance. All costs will be paid for by the Sponsor of this study.
- You, the public health plan, or your personal medical insurance (if any) should continue to pay for expenses for your current medical care and/or prescriptions. These expenses will not be paid as part of your participation in this study.
- The Sponsor of this study is paying your study doctor for the time, effort, and expenses to conduct this study.

Compensation For Participation

For your time and participation in the study, you will be compensated a total of $750 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 2 and received study product), the compensation breakdown is as follows:

- Visit 1 (Screening): $0
- Visit 2: $225
- Visit 3: $250
- Visit 4: $275

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 within 20 business days. An early termination visit will be requested where you will bring back all study-related materials and be requested to complete some blood work and visit procedures if you consent to doing so. If you complete the early termination visit, you will be compensated $50.

Compensation And Treatment for Injury

- In case of an injury or illness suffered while, and solely as a result of participating in this study, you will receive appropriate medical care. The Sponsor will cover necessary medical costs not covered by the provincial health plan or your private medical insurance (if any). By signing this form, you are not giving up your legal rights, nor releasing the study doctor or Sponsors from their legal and professional obligations.

- Be aware that the provincial health plan or your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

Confidentiality of Records

- Staff at KGK Science (the contract research organization managing this study) will keep all your medical information confidential to the extent permitted by law.
- All research data (health information, past medical history, and test results from this study) will be kept in a secured location or server. Forms on which your information is entered will not contain your name (except for external requisitions if applicable)
- Any of your personal information that is stored electronically will be password protected, accessible only to authorized personnel and coded wherever possible. Electronic data may be stored on secure servers which are physically located in Canada and/or the United States.
- You will not be identified in any publication that might result from the study. Unless required by law, only the following may have access to confidential study data (not your personal information) at the study site:
    - The study doctor and study staff
    - The Sponsor (including its monitors and auditors)
    - Members of the Research Ethics Board - Univo REB (an independent ethics committee that reviewed the ethical aspects of this study to help ensure that the rights and welfare of participants are protected and that the study is carried out in an ethical manner)
    - Government regulatory authorities including Health Canada and other foreign regulatory agencies.
- While the Sponsor will not have access to your personal identifying information, the study doctor, study staff, monitors, auditors, REB, and regulatory authorities may review study records, which could include your personal identifying information (such as the signed consent form) for compliance and verification purposes.
- All study data will be archived for a minimum of 15 years from the date of completion of the study in accordance with Health Canada regulatory requirements.
- Information from this study will be submitted to the Sponsor. Information sent from the study site will not contain your name.
- You have the right to check your study records and request changes if the information is incorrect.
- While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.
- As part of this research, you may be required to use one or more of the following: a phone or web app/site, an electronic study diary (eDiary), or a device that tracks information about you. While using these, information about you may be collected and shared with the researchers or people outside of the study. This data might include personal health information, location, call logs, text message history, web browsing history, or social media use. A complete description of the data collection and sharing for an app, eDiary, or device can commonly be found in the Terms of Use, End User License Agreement, or Privacy Policy associated with the device. If you would like to read these documents, request a copy or instructions about how to access this information from the study doctor.

- While the Terms of Use, End User License Agreement, or Privacy Policy may include statements limiting your rights if you are harmed as a result of your use of the app, eDiary, or device in this study, you do not release the investigator, sponsor, institution, or agents for responsibilities from mistakes. You also do not waive any of your rights as a research participant.

By signing and dating the consent form, you give your consent to collect, use and disclose your health information as described above.

A description of this clinical trial will be available on https://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Future Use of Data and Specimens

- Your personal information and/or biospecimens collected during this study may be stored and used for future research. If so, any 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 them or identify you.
- Study doctors, including study doctors from collaborating institutions, can request this data and samples 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.

Future Contact

By participating in this study, you agree that the study staff may contact you in the future should additional information be needed. This contact would only occur if more data specifically related to your participation in this study were required after you have completed the study, or the study has concluded/expired. Any additional information gathered will be handled with the same confidentiality and privacy protections outlined in this consent form. You may choose not to provide additional information if contacted in the future, without any penalty or effect on the care or benefits you receive.

Whom To Contact About This Study

You can contact the study staff via email or by telephone listed on the first page of this document during the study if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study and inform the KGK Science study staff.

A research ethics board (REB) is an independent committee that helps to protect the rights and welfare of research participants. If you have any questions about your rights and welfare as a research participant, or have concerns or complaints regarding this research study, please contact Univo REB at (919) 910-7743 or via email at info@univo-group.com.

Voluntary Consent to Participate

By signing and dating this document I agree that I have been provided enough time to read and consider whether to participate. I have reviewed and understand all pages of the consent form and information it contains regarding the study in a language I understand. I have been given the opportunity to ask all my questions regarding the study with answers to my satisfaction. I understand that I may consult with the study staff, should anything become unclear or if I have further questions.

I volunteer to be in this study at my own free will and without being pressured by the study doctor or the study staff knowing I have the opportunity to leave at any time without giving a reason and without affecting my health care. I understand that if I choose to withdraw from the study, I must notify the study staff. The risks involved with participating in this study are clear to me. I agree to follow the study instructions provided to me by the study staff and understand I may not participate in another study while I am enrolled in this study.

It is clear to me that my data derived from this study will be kept anonymous and may be reviewed by the Sponsor, their agents, Research Ethics 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 record.

IN THE EVENT THAT ELECTRONIC CONSENT IS NOT AVAILABLE:
By signing this informed consent document, you acknowledge that you have read and fully understand all pages of the information presented in it, had enough time to consider this information, had an opportunity to ask questions, and voluntarily agree to be in this study.

_____
Printed Name of Participant

_____ _____ _____AM/PM
Signature of Participant Date (MMM,DD,YYYY) Time (HH:MM)

I attest that the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

_____
Printed Name of Person Explaining Consent

_____ _____ _____AM/PM
Signature of Person Explaining Consent Date (MMM,DD,YYYY) Time (HH:MM)

FOR ELECTRONIC CONSENT:
For electronic consent, your name, digital signature, date and time of consenting will be added below by the consenting software. By adding your electronic signature, you consent to the material provided as if you were physically signing a hard copy of this document. By signing this informed consent document, you acknowledge that you have read and fully understand all the pages of the information presented in it.

Participant
I voluntarily agree to
participate in this study
↓