PARTICIPANT INFORMATION AND CONSENT FORM

Sponsor/Study Title:	LifeWave Inc./ "A randomized, triple-blind, placebo controlled, parallel clinical trial to investigate the efficacy and safety of X39 on muscular strength and endurance in healthy older adults"
Protocol Number:	25LWCRL01
Principal Investigator: ***(Study Doctor)***	David Crowley, MD
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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.

If you wish to contact the study staff, please use the phone number or email address provided at the top of this page.

Background and Purpose

Maintaining mobility and independence is essential for healthy aging. As people grow older, muscle endurance and strength tend to decrease, particularly in those with sedentary lifestyles. This study is being conducted to evaluate the efficacy and safety of a non-transdermal patch (a patch that does not release any medication into the body) called X39, developed by LifeWave Inc., in improving muscle strength, endurance, wellness, and recovery in older adults. Efficacy means how well a product does what it is supposed to do.

The LifeWave X39 patch uses a technology called photobiomodulation (PBM). The body's natural heat (infrared energy) activates the patch's materials to stimulate biological responses when placed on the skin at acupuncture points. This is non-invasive and does not put any chemicals or drugs into the body.

Previous studies on the LifeWave X39 patch suggest improvements in biological markers linked to tissue repair, with potential anti-inflammatory and antioxidant effects. However, more research is needed to understand the effects of LifeWave X39 patch on muscle strength, endurance, and recovery in healthy older adults.

Study Population

This study will include 50 healthy males and females aged 50 years and older.

How Long Is the Study?

If eligible and enrolled in the study, your participation in this study will last approximately 28 days.

Study Design

The study design explains how the study will be done. This is a randomized, triple-blind, placebo controlled, parallel study.

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

- LifeWave X39 patch group
- Placebo patch group

Neither you nor the study staff will be able to choose which group you are in so that the random assignment is fair and unbiased. You will have an equal chance of being assigned to either group.

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 a patch that looks like the one being studied but has no active ingredients or technology. It is used in research to help determine whether the study product has real effects beyond what might happen by chance or expectation.

Parallel — You stay in the same randomly assigned group for the entire study. For example, if you are assigned to the LifeWave X39 patch or placebo group, you stay in that group throughout the entire study.

Important Things to Note

- If you voluntarily agree to participate in this study, you must be willing to:
  - ✓ Perform in-clinic and at home exercises as instructed by the study staff.
  - ✓ Avoid using muscle recovery tools, devices, or other therapies.
  - ✓ Maintain your current lifestyle habits (including diet, medications, supplements, and sleep) throughout the study.
- You should not participate in the study if you:
  - × Have tattoos, skin conditions or sensitive skin on both areas of patch application (back of the neck and below the belly button)
  - × Have engaged in more than 60 minutes of structured exercise per week within the last three months.
  - × Have, or have ever had, a musculoskeletal injury or medical condition that would prevent you from doing the required exercises.
- 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 50 participants have enrolled and started the study, no additional participants will be accepted.

What Will Happen During This Study?

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

Assessments and Procedures

Urine Samples – Visit 1 and 4

- Individuals of child-bearing potential will be required to provide a urine sample for a urine pregnancy test. You will be provided with a collection container and instructed on how to provide the sample.

Questionnaires:

RAND Short Form Health Survey (SF-36) – Visit 1, 2, 3, and 4

- This self-reporting questionnaire assesses health-related quality of life, including physical functioning, role limitations due to physical and emotional health, pain, general health, energy/fatigue, social functioning, emotional well-being, and health transition.

Delayed Onset Muscle Soreness (DOMS) Questionnaire – Visit 1, 2, 3, and 4

- This questionnaire evaluates muscle soreness 24 hours after you finish the exercise done at the clinic.

Physical Activity Readiness Questionnaire (PAR-Q) – Visit 1

- This screening questionnaire helps determine if it is safe to begin or increase physical activity or if medical clearance is needed before participating.

Maximum Seated Push-Up Test – Visit 1, 2, 3, and 4

- You will place your hands on the armrests of a chair. When ready, you will straighten your arms to lift your body off the chair, then lower yourself back down. You will repeat this until you cannot continue.

Timed Plank Test – Visit 1, 2, 3, and 4

- You will be shown how to do the plank and given instructions. When ready, hold a straight, stable position with your shoulders and elbows at 90°, for as long as you can. The test ends when you stop or can't keep the correct form.

30-Second Sit-to-Stand Test – Visit 1, 2, 3, and 4

- You will sit on a chair with your feet flat on the floor and your hands crossed on your chest. Then, you will stand up and sit down as many times as you can in 30 seconds.

Hand Dynamometer Test – Visit 1, 2, 3, and 4

- We will test your handgrip strength on both hands. You'll need to hold the device with your elbow at your side and squeeze as hard as you can when told. This will be done three times per hand with 15 seconds rest between.

Modified Bruce Protocol Treadmill Test – Visit 1, 2, 3, and 4

- You will start by warming up on the treadmill for five minutes at a slow walking pace. Then, you will complete a 7-stage treadmill test that gradually gets harder until you choose to stop.

At-Home Training Program

- You will be given detailed guidelines to complete these training sessions at home three times a week on non-consecutive days, along with 20 minutes of low-to-moderate physical activity every day. Each session will consist of a warm-up, full-body workout, and cool-down.

Warm-up and cool-down	Full Body Workout	Daily Physical Activity
It will include 5-10 minutes of full body stretching (isometric or dynamic) and low intensity exercise, such as: • Walking on the spot or outside • Jogging on the spot or outside	Exercises to be completed during each training session: • Bodyweight squats • Bodyweight pushups* • Bodyweight plank • Palm squeeze (handgrip device)* **Exercise modifications available*	You will be instructed to complete 20 minutes of low-to-moderate physical activity throughout the day. Examples include: • Walking • Biking • Swimming • Dancing

- You will also receive specific instructions on which exercises to do and how to perform them correctly.
- For each exercise, you will complete three sets. You will do continuous repetitions until you reach fatigue (cannot keep proper form).
- The goal is to progressively increase the maximum number of repetitions for bodyweight squats, bodyweight pushups, and palm squeeze exercises, or increase the time you can hold a plank

Resting periods:

- Approximately **1 minute between sets**
- Approximately **2 minutes between exercises**

Exercise modifications:

- *Modified pushups*: Start with modified pushups (knees on the floor) until you can do 10 repetitions with good form. Once you're able to complete 10 repetitions with proper form, progress to regular pushups (feet on the floor) until you reach failure.
- *Modified palm squeeze*: Choose a resistance on the handgrip device that makes you reach fatigue in 8–12 repetitions. Increase resistance if you can do 12 repetitions with good form. Once at the highest resistance, keep going until fatigue.

Food Records

- You will use an online food records application to log your food and drink intake for three days—two weekdays and one weekend day—during the week after Visit 1 and again the week before Visit 4.

Study Diary

- You will complete an online daily study diary throughout the study (Starting at visit 1). Questions about study product use, lifestyle habits, any changes in medications and/or health, and details about your at-home training program will be included.

Schedule of Study Visits

Visit 1 – Screening/Baseline *Some portions of this visit may occur virtually*
• Informed consent obtained • Review of medical history, medications, current health status, and any changes in health • Urine pregnancy test (for individuals of childbearing potential) • Seated resting Blood Pressure (BP) and Heart Rate (HR) measurements • Weight and height measurements (BMI calculation) • Completion of the PAR-Q • Potential eligibility will be assessed. If you still meet all study requirements and are eligible, you will be randomized (randomly assigned to one of the study groups). • Completion of seated push-ups, timed plank, 30-second sit-to-stand, handgrip strength assessments, Modified Bruce Protocol, and RAND SF-36 questionnaire. • You will receive the study product, a study diary, 3-day food records, and the at-home training program, along with instructions for each. ***DOMS questionnaire to be completed at home 24 hours after in-clinic exercise.***

Visit 2 (Day 7 ± 2 Days) and Visit 3 (Day 14 ± 2 Days)
You will return to the clinic with completed study diary, food records (only at Visit 2) and any unused study product • Review of completed 3-day food records (only at Visit 2), diaries, medications, and changes in health. • Seated resting BP and HR measurements • Weight measurements • Completion of seated push-ups, timed plank, 30-second sit-to-stand, handgrip strength assessments, Modified Bruce Protocol, and RAND SF-36 questionnaire • Clinic staff will count the returned study product to confirm you have taken it as directed • You will receive new study product, study diaries, and 3-day food records (food records will be given to you only during your Visit 3 and will be completed the week before your Visit 4) ***DOMS questionnaire to be completed at home 24 hours after in-clinic exercise.***
Visit 4 End of Study (Day 28 ± 2 Days)
You will return to the clinic with completed study diary, food records and any unused study product • Review of completed 3-day food records, diaries, medications, and changes in health. • Urine pregnancy test (for individuals of childbearing potential) • Seated resting BP and HR measurements • Weight measurements • Clinic staff will count the returned study product to confirm you have taken it as directed • Completion of seated push-ups, timed plank, 30-second sit-to-stand, handgrip strength assessments, Modified Bruce Protocol, and RAND SF-36 questionnaire ***DOMS questionnaire to be completed at home 24 hours after in-clinic exercise.***

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

Individuals able to become pregnant (not post-menopausal for the past 1 year, 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/baseline 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 patch form.

LifeWave X39 patch

Ingredients: The patches are made of water, stabilized oxygen, stereoisomers (different forms of the same molecule) of organic sugars and stereoisomers of amino acids.

The mix of these materials is placed in a sealed pouch made from medical-grade polyethylene plastic. One side of the patch has a hypoallergenic, medical-grade adhesive that allows it to stick to your skin or clothing.

Placebo:

Ingredients: Laminate film, non-woven material, adhesive medical tape with backing, distilled water

Directions:

- You will be instructed to keep the patches in a cool room or room temperature area. Do not leave them in a hot car or room for an extended period of time.
- Please maintain the same site of application and same time of day the patch will be applied and removed for the entire duration of the study.
- Beginning on Day 1 (the day after your first visit), you will apply the patch to the back of the neck or directly below the bellybutton on **clean, dry skin** first thing each morning and remove after 12 hours or before going to bed. Make sure you skin is clean and dry before applying the patch. If the patch gets wet after it is applied, it will continue to work.
- If the patch falls off over the course of the 12 hours, clean and dry the application site and reapply a new patch for the remainder of the 12-hour daily wear.
- Document in your diaries the number of patches used each day, the time of day the patch is applied (as well as reapplied, if necessary) and removed, the total daily wear time, and the part of the body where you applied the patch.
- If you forget to apply the patch on one day, apply it as soon as you remember and wear it for 12 hours or the remainder of the day until you go to sleep.
- Do not wear the patch for more than 12 hours each day.
- If you forget to remove the patch and wear it longer than approximately 12 hours, remove it as soon as you remember.
- Save all unused and open study product packaging and return them to the clinic at each study visit.

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 study products that nobody knows about yet. There may be unknown risks with using the study products. Potential side-effects of using the study products may include:

- Allergic skin reactions or sensitivity to the adhesive including: Itching, redness, irritation of the skin.

Ensure proper skin cleaning and drying before applying the patch. If you experience redness or skin irritation around the area where the patch is applied, remove it immediately and contact study staff. If symptoms persist longer than 2-3 days of not using the patch, seek medical attention and inform study staff.

A possible risk of the exercise program is musculoskeletal injury (such as muscle or joint strain).

If you think you are experiencing a side effect, you should also report it in your study diary.

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, you could die. Read the study ingredients carefully to make sure you are not allergic to any of them. Some effects of an allergic reaction that could be a sign of a life-threatening (anaphylaxis) include:

- Rash
- Difficulty of Breathing
- Wheezing
- Sudden drop in blood pressure (making you feel dizzy or lightheaded)
- Swelling around the mouth, throat, or eyes
- Fast pulse
- Sweating

If you experience any of the above-listed effects or any other side effects during the study, you should get medical help or go to the emergency room immediately and then contact the study staff. Refer to section “Whom to Contact About This Study” for instructions on what to do in case of an emergency.

Contact the study staff if you have questions about the signs or symptoms of any side-effects you read about in this consent form. Inform the study staff right away if you experience any side-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.

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 complete 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 using 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

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 $600 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). Compensation will be processed and received approximately 20 business days from the date you complete the study. Processing times may apply before funds become available on your ClinCard.

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

- Visit 1: $100
- Visit 2: $ 125
- Visit 3: $ 175
- Visit 4: $ 200

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 complete some questionnaires 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 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 - 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 application/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 application, 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 application, 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

- 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 identify you.
- Study doctors, including study doctors from collaborating institutions, can request this data for new research. Data may also be shared with outside non-profit academic study doctors as well as with for-profit study doctors or commercial entities, with whom we collaborate.
- You will not be asked to provide additional informed consent for the use of your de-identified information in future research.

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 is 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 with enough time to read and consider whether to participate. I have reviewed and understood 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

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