PARTICIPANT INFORMATION AND CONSENT FORM

Sponsor / Study Title:	**Quicksilver Scientific / "A randomized, single-blind, controlled, parallel clinical trial to examine the efficacy and safety of an investigational product with and without use of semaglutide on glycemic response in adults with prediabetes or Type 2 Diabetes"**
Protocol Number:	**24QSCFA02**
Principal Investigator: (Study Doctor)	**David Crowley, MD**
Telephone:	**519-438-9374 (24 Hour)**
Address:	**KGK Science Inc** **275 Dundas St** **G02** **London, ON N6B 3L1**

THIS IS AN IMPORTANT DOCUMENT – KEEP FOR FUTURE REFERENCE

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 on the first page of this form.

Background And Purpose

Diabetes is associated with an increased risk of heart and blood vessel diseases, making it important to manage the condition early, even before it fully develops. Healthy eating and regular physical activity are often the first steps in managing glycemic (blood sugar) levels, but some people may also need medications such as semaglutide (Ozempic®), a glucagon-like peptide-1 (GLP-1) receptor agonist, to keep their blood sugars under control.

Semaglutide is indicated for treatment of adult patients with type 2 diabetes to improve glycemic control. **Semaglutide is not indicated for the treatment of prediabetes.**

Serious Warnings and Precautions - Possible Risk of thyroid tumours, including cancer
As part of drug testing, semaglutide, the active ingredient in OZEMPIC® was given to rats and mice in long term studies. In these studies, semaglutide caused both rats and mice to develop medullary thyroid tumours, some of which were cancer. It is not known if semaglutide will cause thyroid tumours or a rare type of thyroid cancer called medullary thyroid cancer in people.
Do not use OZEMPIC® if you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC), or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). While taking OZEMPIC®, tell your doctor if you get a lump or swelling in your neck,
hoarseness, trouble swallowing or shortness of breath. These may be symptoms of thyroid cancer. You should discuss any safety concerns you have about the use of OZEMPIC® with your doctor.

Previous studies suggest that the individual ingredients of the study product AMPK Charge+®, a dietary supplement, may improve blood sugar levels. The purpose of this study to investigate the safety and efficacy of AMPK Charge+® supplementation with and without semaglutide therapy on glycemic response in adults with prediabetes or Type 2 Diabetes (T2D).

Study Population

This study will include about 90 adults aged 18 years or older with prediabetes or Type 2 Diabetes.

How Long Is the Study?

If eligible after the screening visit, your participation in this study will last approximately 84 days.

Important Things to Note

- If you voluntarily consent to participate in this study, you must:
  - Agree to maintain your current lifestyle habits as much as possible throughout the study
  - Be willing to complete questionnaires, records, and diaries associated with the study and to complete all clinic visits
  - Be willing to fast (no food or drink, except water) for at least 12 hours before visit 2, 3 and 4
- 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 90 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.

What Will Happen During the Study?

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

Assessments and Procedures

Randomization *– Visit 2*

Randomization means you will be assigned by chance (like flipping a coin) to a study group. If eligible, you will be randomized to 1 of 2 groups:

- AMPK Charge+®
- AMPK Charge+® with Semaglutide (Ozempic®)

Neither you nor the study staff will be able to pick which group you are in, ensuring the integrity of the study. You will have a 50% (1 in 2) chance of receiving AMPK Charge+® and a 50% (1 in 2) chance of receiving AMPK Charge+® with Semaglutide (Ozempic®). This is a single-blind study which means the researchers analyzing the data will not know which group you have been randomized to.

Urine *– Visit 1, 2, 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.

Blood Samples *– Visit 1, 2, 3, 4*
The total blood volume collection will be approximately 300 mL (approximately 20 tablespoons), over the period from screening (Visit 1) to the end of the study (Visit 4) (approximately 132 days). At any study visit, blood volume collected is not expected to exceed 120 mL (approximately 8 tablespoons). If needed, additional blood samples may be collected during the course of the study in order to perform or repeat laboratory tests.

Blood will be collected using both conventional phlebotomy (blood draw from a vein using a needle) or intravenous (IV) catheterization (placing a small flexible tube into a vein) techniques, depending on the visit requirements. The catheter will be flushed with saline to keep it clear and working properly throughout the visits.

Oral Glucose Tolerance Test (OGTT) *– Visit 2 and 4*
This test begins with a fasting blood sample to measure glucose and insulin levels. Afterwards you will drink a glucose solution containing 75 grams of sugar. Additional blood samples will be collected at 15, 30, 45, 60, 90, and 120 minutes after you drink the solution to monitor your body's response to the glucose.

Study Diary
You will complete an online study diary daily throughout the study. Questions about study product use, lifestyle habits and any changes in health will be included.

Framingham Cardiovascular Risk Score (FCVRS)
Study staff will use this FCVRS tool to estimate your risk of developing heart-related problems over the next 10 years. This tool considers factors such as your age, sex, blood pressure, whether you are receiving treatment for high blood pressure, whether you smoke, whether you have diabetes, and your cholesterol levels (both total cholesterol and HDL cholesterol).

Schedule of Study Visits
You are required to fast for at least 12 hours prior to Visit 2, 3 and 4.

Visit 1 – Screening *Some portions of this visit may occur virtually prior to coming into clinic*
After informed consent is obtained, the screening assessments will include: • Review of medical history, medications, current health status, any changes in health • Urine pregnancy test (if applicable) • Seated resting Blood Pressure (BP) and Heart Rate (HR) measurements • Weight and height measurements (Body Mass Index (BMI) calculation) • Blood samples • Potential eligibility will be assessed

Visit 2 – Enrollment (Day 0)
• Review of medications, current health status, and any changes in health • Urine pregnancy test (if applicable) • Seated resting BP and HR measurements • Weight measurements (BMI calculation) If you still meet all study requirements and are eligible, you will be randomized and undergo the following assessments: • Blood samples • OGTT • Study diary, study product and instructions will be given • If randomized to AMPK Charge+® with semaglutide group, study staff will provide an education session to ensure you are comfortable with study product procedures
Visit 3 (Day 42 ± 2 days)
• Return all unused and opened study product packaging, along with completed study diaries • Review of medications, any changes in health, and study diaries • Returned study product will be reviewed for compliance calculation • New study diaries and study product will be dispensed • Seated resting BP and HR measurements • Weight measurements (BMI calculation) • Blood samples
Visit 4 – End of Study (Day 84 ± 2 days)
• Return all unused and opened study product packaging, along with completed study diaries • Review of medications, any changes in health, and study diaries • Urine pregnancy test (if applicable) • Seated resting BP and HR measurements • Weight measurements (BMI calculation) • Blood samples • OGTT

Medications, Supplements, And Food/Drinks

If you are taking any prescribed medications, you must agree to maintain you dosing regimen during the study, unless otherwise recommended by your general/nurse practitioner. If they recommend any medication or dose changes, please notify the study staff immediately. You should not discontinue your regular medications unless explicitly instructed by your general/nurse practitioner. Stopping regular medications without medical advice to join this study may worsen your health. If you stop your regular medications, inform the study staff immediately.

- There are some prescribed medications, and or treatments that are not permitted during the study. If you are taking any of these prescribed medications and/or treatments, you may only be assessed for eligibility if you have been taken off these therapies by your

general/nurse practitioner. The study doctor will recommend an appropriate washout period prior to enrollment in the study.
- There are some over-the-counter medications, supplements and/or foods and drinks that are not permitted during the study. If you use any these over-the-counter medications, supplements and/or foods and drinks, you must be willing to stop taking them and agree not to consume these items during the study. The study doctor will recommend an appropriate washout period prior to enrollment in the study.

***Washout Period*:** This is a period of time recommended by the study doctor to allow restricted substances (such as medications, supplements, foods, or drinks) to clear from the body before the study begins. 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 screening and 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

AMPK Charge+®

The study product will be in a liquid form.

Ingredients

Medicinal Ingredient	Quantity
Diindolylmethane (from indole)	40 mg
95% Quercetin (Sophora japonica flower)	38 mg
Milk Thistle Seed Extract (Silybum marianum, 80% Silymarin)	40 mg
Resveratrol (Polygonum cuspidatum root)	40 mg
Berberine (Phellodendron amurense bark)	10.86 mg

Non-medicinal ingredients: Phosphatidyl choline, glycerin, water, ethanol, medium chain triglycerides, tocofersolan, natural citrus oils, natural flavouring, natural mixed tocopherols, propolis extract, cinnamon flavour and thaumatin.

Directions for AMPK Charge+®

- Using the provided measuring tool, you will take 1 teaspoon (5 mL) of the study product on an empty stomach before breakfast and 1 teaspoon on an empty stomach in the afternoon starting on Day 1 (the day after Visit 2)
- You will hold the study product in your mouth for about 30 to 90 seconds before swallowing
- If you miss a dose, take the missed dose as soon as you remember
- Do not exceed 10 mL at one time and 20 mL a day
- Store the study product at room temperature and avoid exposure to direct sunlight or heat
- You will save all unused and open study product packaging and return them to the clinic at each study visit

Semaglutide (Ozempic®)

Semaglutide will be in a pre-filled injection pen and will only be dispensed to the AMPK Charge+® with semaglutide randomized group.

Ingredients

Medicinal Ingredient	Quantity
Semaglutide (subcutaneous injection)	0.25-0.5 mg
Non-medicinal ingredients: Disodium phosphate dihydrate, propylene glycol, phenol, and water for injections	

Storage
You will be required to protect the study product from freezing, and excessive heat and light. If the study product has been frozen, do not use it. Keep the pen cap on when the study product is not in use to protect it from light. Below is a table outlining storage instructions:

Prior to first use	**After first use**
Refrigerated 2°C to 8°C	Room temperature below 30°C or Refrigerated 2°C to 8°C
Until expiration date	8 weeks

Directions for Semaglutide (Ozempic®)

How to Administer	Subcutaneously – beneath the skin
Frequency	Once per week
Dosing Schedule	• Begin with **0.25 mg** once per week for the first 4 weeks • Increase to **0.5 mg** once per week for the remainder of the study period
Titration Error Instructions	• If you administer less than your scheduled weekly dose, please administer the remaining dose within the next five days. For example, if you administered 0.25 mg instead of 0.5 mg in Week 5 or later, administer the remaining 0.25 mg within five days of your scheduled dose
Missed Dose Instructions	• Administer the missed dose as soon as possible within 5 days after the scheduled dose • If more than 5 days have passed, skip the missed dose and administer the next dose on your regular dosing day
Resuming Schedule	After a missed dose, return to the regular once-weekly dosing schedule
Important Note	Do not take more than the directed weekly dose
Return Study Product	You will save all unused and used study product packaging and return them to the clinic at each study visit

During Visit 2, study staff will provide an educational session and instructions for safe storage including removal of the injection needle immediately after each injection and storing the study product without a needle attached to minimize risk of damage, contamination, infection, leakage, and inaccurate dosing.

Alternative Treatments

You do not have to be in this study to receive treatment for your prediabetes or Type 2 Diabetes/ There are other treatment options instead of participating in this study. Lifestyle changes, including diet, exercise, and weight management, as well as alternative pharmacological or natural health treatments, may be options that you can discuss with your regular doctor or the study doctor. These alternatives may offer potential benefits and risks that should be considered in consultation with your treating healthcare professional.

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 doctor 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 product that nobody knows about yet. There may be unknown risks with taking the study product. Potential side-effects of taking the study product (AMPK Charge+®) may include:

- Abdominal discomfort such as pain, nausea, diarrhea, vomiting, constipation, flatulence, bloating
- Drop in blood sugars (e.g., sweating, paleness, chills, headache, dizziness and/or confusion)
- Liver related symptoms such as yellowing of eyes and/or skin, dark urine, abdominal pain, jaundice
- Low estrogen symptoms such as joint pain, mood changes, changes in libido, hot flashes, night sweats, vaginal dryness or irregular menstruations

Potential side-effects of taking Semaglutide (Ozempic®) may include:

- Abdominal discomfort such as pain, nausea, diarrhea, vomiting, constipation
- Increased heart rate
- Dizziness
- Injection site reaction (e.g., redness, swelling, itching, bruising, pain, or tenderness)

Stop use and ask a health care practitioner if you experience sweating, paleness, chills, headache, dizziness and/or confusion (as these may be symptoms of serious low blood sugar).

If you experience nausea, here are some general nausea tips that you might find helpful:

- Eat bland, low-fat foods, like crackers, toast, and rice
- Eat foods that contain water, like soups and gelatin
- Avoid fried, greasy, or sweet foods
- Avoid lying down after you eat
- Go outdoors for fresh air
- Eat more slowly
- Drink clear or ice-cold drinks

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, you could die. Please 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. Please also 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.

Please inform the study staff right away if you experience any side-effect, 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 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 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 $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). 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:

- Screening Visit 1: $0
- Visit 2: $150
- Visit 3: $175
- 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. 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.
- As part of this research, the study doctor will collect the results of your study-related tests and procedures and may also access your personal medical records for health information such as past medical history and test results.
- All research data (health information, past medical history, and test results from this study) will be kept in a locked file. 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 identifying information) at the study site:
    - The study doctor and study staff

  - The Sponsor (including its monitors and auditors)
  - Members of the Research Ethics Board (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 where the study drug may be considered for approval
- 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. By signing this information and consent form, you consent to the collection, access, use and disclosure of your information as described above.
- 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 staff.
- 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.

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 http://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 research studies may include genetic research. Your genes are unique to you. At this time, you cannot be identified through this research. There is a risk that you might be reidentified in the future as genetic research progresses. The main risk associated with genetic analysis is misuse of personal genetic information. A federal law, called the Genetic Non-discrimination Act (GNA), prohibits genetic discrimination across Canada. It bars any person from requiring you to undergo and disclose the results of a genetic test as a condition of providing goods or services, or entering into a contract, however, the law exempts health care practitioners and researchers. The genetic testing in this research is optional. As per GNA, you are not required to disclose the genetic results to others, including employers or insurance companies. The Confidentiality section of this document explains the precautions that will be taken to keep your genetic information confidential. However, absolute confidentiality cannot be guaranteed.

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

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;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

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

An Institutional Review Board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00091097.

Primary Health Care Provider Notification Option

If you consent to having your family doctor or primary health care provider notified, please inform the study staff.

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 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 must 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, the Institutional Review Board (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 will receive a copy of this signed and dated consent form and am expected to keep a copy 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 pages of the information presented in it.

Participant

I voluntarily agree to participate in this study
↓