RESEARCH PARTICIPANT INFORMED CONSENT DOCUMENT	
Sponsor:	**Altamira Medica AG**
Study Title:	**A Pivotal, Randomized, Open-Label, 3-Period Crossover Study to Assess the Efficacy and Safety of AM-301 on Allergic Symptoms During House Dust Mite Challenge in an Environmental Exposure Chamber in Study participants with Perennial Allergic Rhinitis**
Protocol Number:	[redacted]
Principal Investigator: (Study Doctor)	[redacted]
Telephone:	[redacted]
MON-FRI (9:00 AM – 5:00 PM)	**Please use this number for general inquiries, returning voicemails and any questions you may have. Voicemail is available.**
After-Hour Contact	[redacted]
Site Address:	[redacted]

***Inflamax Research Limited doing business as Cliantha Research.**

1. INFORMED CONSENT DOCUMENT

This document, called an informed consent document (ICD), provides clinical study participants with information about the clinical study and the investigational product used in this study. It also explains:

- Your rights and responsibilities as a study participant
- What you will be asked to do
- The potential risks you should be aware of before deciding whether or not to participate in this study.

Please take the time to read this document and ask as many questions as you like. The study doctor and/or study staff will be available and happy to answer any questions you may have. Please take the time to read and consider the following information and seek advice from a doctor or others before deciding whether or not to take part in this research study. You are under no obligation to participate, and your decision to take part is voluntary.

If you agree to participate in this study, you will be asked to sign and date the document's signature page (last page). You will be given a copy of your signed and dated ICD to keep. You have the right to change your mind about participating in this study. If you decide to stop participating at any time during the study, just let the study doctor or study staff know as soon as possible.

You must be honest and complete in providing your health and medication history. Giving incorrect, incomplete, or misleading information may have serious health consequences for you. For your safety, it is very important to tell the study doctor about all of the medications you have taken or are currently taking, including herbal or natural remedies.

2. INTRODUCTION

2.1 NATURE/PURPOSE OF THE STUDY

You are being asked to volunteer for a medical research study at Cliantha Research because you are allergic to house dust mites (HDM). HDM, a predominant source of indoor aeroallergen worldwide, has been associated with allergic diseases since 1920. HDM-induced allergic diseases include allergic rhinoconjunctivitis, allergic asthma, atopic eczema and other allergic diseases. Some of your allergy symptoms can include an itchy nose, nasal congestion (stuffy nose), runny nose, and sneezing.

The primary purpose of this study is to compare the effectiveness of Altamira Medica's AM-301 (marketed in Europe as Bentrio) device between study participants who are administered AM-301 and those who are not administered AM-301, in the treatment of Perennial Allergic Rhinitis (PAR). AM-301 is not marketed in Canada.
There will be two different study treatments with this device which will be compared to one another.

The AM-301 nasal spray is used to treat allergic rhinitis and hay fever. It reduces exposure to airborne (transported by air) allergens and increases the relief of allergic symptoms when inhaling airborne allergens. It is not working as a drug product. The main element in AM-301 is bentonite. Bentonite is a mineral clay that can be found in nature. It is mainly composed of montmorillonite. Following application with a spray, AM-301 forms a physical protective barrier (gel layer) on the nasal mucosa, traps airborne particles and moistens the nasal mucosa and thus aids its function. This triple protective effect helps in the defense against airborne particles. All ingredients of the AM-301 formulation are well-established and generally recognized as safe.

The Test product is made by a company called Altamira Medica who is also sponsoring the clinical study. Cliantha Research is doing the study on behalf of Altamira Medica. The Sponsor will financially compensate the study doctor and Cliantha Research for the time and effort to conduct the study.

Data from this study may be submitted to a government regulatory authority to obtain approval to market the Test product. Data may also be used to prepare a publication.

2.2 LENGTH OF THE STUDY AND THE NUMBERS OF VOLUNTEERS EXPECTED TO PARTICIPATE

Approximately 36 males and non-pregnant females, ages 18 to 65 years at the time of Screening, with a history of PAR, will take part in this study. This study will include 5 study clinic visits over approximately 65 days, including Medical Screening, Environmental Exposure Chamber (EEC) Screening and 3 StudyTreatment visits. If you pass the screening procedures and are enrolled in the study, your participation in this study will last up to approximately 19 days. The 4 EEC sessions will be separated by at least 7 days. During the study, you will undergo 4 visits to the EEC located at Cliantha Research in Mississauga, Ontario.

There will be 5 planned Study Clinic appointments and a follow-up telephone contact.

1. Screening Visit 1 (Day -28 to Day -1)
2. EEC Screening Visit 2 (Day 1)
3. Study Treatment Visit 3 (Day 8)
4. Study Treatment Visit 4 (Day 15)
5. Study Treatment Visit 5 (Day 22)
6. Follow-up Telephone contact

At all times for your safety, you may be required to remain at the site for longer at the decision of the study doctor or designee.

2.3 STUDY TREATMENT

There are 3 study treatment visits in the study. In each study treatment visit, you will be administered the study product by study staff. The study product is AM-301 Nasal Spray and there are 3 different study treatment groups. as follows:

Study Treatment Groups:

- A: One Spray of AM-301 Device per nostril
- B: Two Sprays of AM-301 Device per nostril (with different spray angles)
- C: No study treatment

You will receive all 3 study treatment options (A, B and C), but at different visits and in a different order. The possible sequences of study treatment are the following:

- ABC

- BCA
- CAB
- ACB
- BAC
- CBA

The order in which you will receive the study device is random (like a dice roll); you have an equal chance of being assigned to any one of the six sequences. For example, you may receive study treatment sequence ABC:

- At Visit 3, you get Study Treatment A (One Spray of AM-301 per nostril)
- At Visit 4, you get Study Treatment B (Two Sprays of AM-301 per nostril)
- At Visit 5, you get Study Treatment C (No Treatment)

Alternatively, you may receive study treatment sequence BCA:

- At Visit 3, you get Study Treatment B (Two Sprays of AM-301 per nostril)
- At Visit 4, you get Study Treatment C (No Treatment)
- At Visit 5, you get Study Treatment A (One Spray of AM-301 per nostril)

This is an open-label study, meaning that you and the study staff will know which study treatment you will receive at each visit.

3 WHAT WILL HAPPEN IN THE STUDY

3.1 SCREENING PROCESS

You are volunteering to participate in a research study at Cliantha Research. Before being enrolled in the study, you must take part in the screening process. During the screening, you will have medical tests performed to help the study doctor decide if you meet the requirements to be enrolled in the study. This does not guarantee that you will participate in the research study, even if you pass the medical examination.

The following activities will be completed at Screening:A government-issued ID containing an image of you or a government-issued non-photo ID with a non-government photograph ID will be used to confirm your identification.

- Signing and dating the Research Participant Informed Consent Document.
- You will be pre-screened based on a COVID-19 Questionnaire, and a nasal swab will be collected.
- Provide a Medical History including details of allergy history, social history (if you drink alcohol and use any drugs) and answer questions regarding your current and past health, any medications you have taken, smoking history, and other general questions about your health and previous study participation.

- Collection of demographic data including date of birth, age, gender, race and ethnicity, measurement of height, weight and BMI.
- A full physical examination will include but not be limited to the head and neck (including nose, eyes, throat and ears), general appearance, skin, lymph nodes, thyroid, musculoskeletal/ extremities, cardiovascular, lungs, abdomen, and neurological system.
- Measurement of vital signs – blood pressure, heart rate, breathing rate and body temperature.
- Blood and urine samples for routine clinical laboratory tests and screens for pregnancy (if you are a woman of childbearing potential only).
- Spirometry (to test your lung function) will be performed. You will breathe into a small machine called a spirometer. The spirometer records the amount of air you breathe in and out and the speed of your breath.
- Nasal examination (nasal mucosa [inner lining of the nose], sinuses and upper airway) will be performed.
- Perform a skin prick test to assess if you have any common allergies, including House Dust Mites (HDM) but not limited to cat, dog, mold, ragweed, grass, or tree pollen. This procedure will involve pricking a small amount of allergy solution(s) into your skin to determine if you have a reaction.

  Note: Previous documented positive Skin Prick Test performed at the research site within 12 months of the screening visit is acceptable.
- Your health status will be monitored throughout the screening process, and if you are unwell, you should let us know.
- You will be evaluated to see if you are eligible for the study based on the inclusion, exclusion and restriction criteria.

3.1.1 COVID-19 SCREENING

The following procedures will be performed as part of COVID-19 screening:

- You will be pre-screened based upon a COVID-19 questionnaire at each visit.
- Oral temperature will be measured at every visit and/or any unscheduled visits.
- A nasal/oral/nasopharyngeal swab will be collected for COVID-19 testing on the day of each visit. You will be allowed to come for the visit only if you test negative.

3.1.2 REVIEW OF MEDICAL TESTING RESULTS

Upon reviewing the information collected during the screening process, the study doctor may request additional tests that may help explain inconclusive results. This may

involve a return to either the study site or an alternative location. Updates to the information collected at screening may be requested up to Visit 2. Test results will become a part of your medical record. If, in the future, you sign waivers to release medical information to insurance companies, employers or any other third party, then Cliantha Research would be obligated to release all medical information to those third parties.

By requirement of local health regulations, any positive infection screen results (for example, COVID-19) will be reported to the local public health. Your full name, address and any other required information will be sent to the local public health together with a copy of the result. If requested, a copy of this signed and dated consent form will also be sent. One of the study doctors or staff will contact you to discuss these results. You will be provided with a copy of the results and be asked to see your family doctor for further medical care. If you do not have a family doctor or choose not to have your results forwarded to your family doctor for follow-up and consultation, a doctor at Cliantha Research will arrange for another doctor/specialist to see you.

3.2 ENVIRONMENTL EXPOSURE CHAMBER (EEC) SCREENING VISIT (VISIT 2)

If you meet the eligibility criteria in the Screening visit, you will participate in a Screening EEC visit where you will be exposed to house dust mites in an EEC.

Visit 2 may take place 28 days after Visit 1. At this visit, you will be tested for your allergies to house dust mites in the EEC. You will be in the EEC for approximately 3 hours.

- A government-issued ID containing an image of you or a government-issued non-photo ID with a non-government photograph ID will be used to confirm your identification.
- You will be pre-screened based on a COVID-19 Questionnaire, and a nasal swab will be collected.
- Before entering the EEC, you will be briefly assessed to determine if you continue to be eligible based on inclusion/exclusion and restriction criteria.
- You will be asked if you have had any changes in health and have taken any other medications.
- Measurement of vital signs – blood pressure, heart rate and breathing rate.
- You will be asked to provide a urine sample for a pregnancy test (if you are a woman of childbearing potential only). A positive or abnormal result will lead to your exclusion from the study.
- Nasal examination (nasal mucosa [inner lining of the nose], sinuses and upper airway) will be performed.
- You will be trained on a tablet device [Electronic Patient Data Acquisition Tablet® (ePDAT®)] on how to rate your symptoms.

- You will be exposed to EEC for approximately 3 hours and asked to fill the total nasal symptom score (TNSS) questionnaire using ePDAT® within 25 min before entering EEC and every 20 min while in the EEC.
- You will be monitored for any changes in your health throughout the EEC session.
- Trained study staff will ask how you are feeling and how the visit went for you.
- Study staff will ask you to return your ePDAT®.

The study doctor and/or study staff will review your symptom scores. Based on your results, you may be contacted by the study site to let you know if you are eligible for the first Study Treatment visit (Visit 3).

3.3 STUDY TREATMENT VISIT 3 (DAY 8), VISIT 4 (DAY 15) AND VISIT 5 (DAY 22)

If you meet the eligibility criteria in Visit 2, you will further proceed to the study (Visit 3, 4 and 5). You will be randomized at Visit 3. The EEC visits (Visit 3, 4 and 5) will occur after at least 7 days after your previous EEC visit. The following study procedures will be performed:

- A government-issued ID containing an image of you or a government-issued non-photo ID with a non-government photograph ID will be used to confirm your identification.
- You will be pre-screened based on a COVID-19 Questionnaire, and a nasal swab will be collected.
- Before entering the EEC, you will be briefly assessed to determine if you continue to be eligible based on inclusion/exclusion and restriction criteria.
- You will be asked if you have had any changes in health and have taken any other medications.
- Measurement of vital signs – blood pressure, heart rate and breathing rate.
- You will be asked to provide a urine sample for a pregnancy test (if you are a woman of childbearing potential only) before entering the EEC. A positive or abnormal result will lead to your exclusion from the study.
- Nasal examination (nasal mucosa [inner lining of the nose], sinuses and upper airway) will be performed before entering the EEC.
- You will be trained on the ePDAT® tablet on how to rate your symptoms.
- Study staff will administer the test product (in the order specified) through the nasal route at your scheduled dosage time. Study treatment (group C) won't be receiving any administration.

- You will be exposed to EEC for approximately 3 hours and asked to fill the total nasal symptom score (TNSS) questionnaire using ePDAT® within 25 min before entering EEC and every 20 min while in the EEC.
- You will be monitored for any changes in your health throughout the EEC session.
- You will be asked a few questions on the medical device used in the study as a part of 'global rating of efficacy of the medical device'.
- Study staff will ask you to return your ePDAT®.
- You will exit the study after completing Visit 5.

3.4 Follow-up Telephone Contact

Following Visit 5 (approximately after 7 days) you will receive a telephone call by the study staff to inquire about any side effects and concomitant medication.

3.5 Environmental Exposure Chamber

If you cannot tolerate the EEC at any visit, you may leave at any time and will be observed in the study clinic. However, leaving early will result in your removal from the study. The following information applies to your EEC visits during this study:

- You are permitted to leave the EEC to use the restroom if required. However, you will be advised not to leave the EEC 10 minutes before or during the sampling session, close to or during your time point symptom assessments, and 30 minutes post-dosing.
- Your restroom breaks will be monitored and documented by study staff.
- You will be asked to follow general rules for EEC, and if you do not comply with these rules, this may affect your continued participation in the study.

3.6 Total Nasal Symptom Score (TNSS)

There are 4 nasal symptoms you will be asked to rate (Itchy nose, nasal congestion, runny nose, sneezing). You will be asked to rate for its severity (none, mild, moderate, severe). You will get trained/re-trained on how to rate them before each EEC session.

Electronic diary and Electronic signature

You will be provided with an Electronic Patient Data Acquisition Tablet® (ePDAT®) during your EEC sessions. This tablet must be returned in order for you to complete your participation in the study. If you damage the tablet, please inform the study staff immediately. The information/data you enter into the tablet will be associated with your electronic signature, which consists of the name and password (e-signature).

Your electronic signature is the legal binding equivalent of your handwritten signature. It will consist of user identification and password. The password is confidential and known only by you. You must not, under any circumstances, give your electronic signature

password to anyone. Please report to study staff if you suspect that your password confidentiality has been compromised and you need to have it reset.

4 SIDE EFFECTS AND OTHER RISKS

4.1 STUDY DRUG

In previous studies with AM-301 there were occurrences of burning sensation. This was thought to be associated with the preservative ingredient which is no longer present in the product. There are potential events associated with nasal inhalers such as infection, bleeding, mucosal changes, mucosal irritation leading to nasal obstruction, sensory changes, and sensitization/allergy but these have not occurred in human studies to date and are not expected due to the differences in application.

Any drug can, very rarely, cause allergic reactions (such as hives, swelling of the face, lips, tongue and/or throat, which may cause difficulty breathing or swallowing) that can be fatal. You will be under medical supervision during EEC visits. If you experience the symptoms of an allergic reaction outside Cliantha facility, please go to the nearest hospital emergency department.

4.2 NASAL SPECULUM EXAMINATION

A nasal speculum is an instrument used to widen the opening of a nostril so the inside of the nose can be seen easily. Risks associated with the use of nasal speculum are slight nasal discomfort, watering eyes, runny nose, sneezing, slight nasal bleeding etc.

4.3 BLOOD COLLECTION

Risks associated with having blood drawn include:

- Bruising
- Swelling or infection at the site where the needle is inserted
- Light-headedness or feeling faint.

If you feel faint, notify the study staff. If you must stand up, please do so slowly or ask the study staff for assistance.

4.4 SKIN PRICK TESTING

The skin prick test procedure involves pricking a small amount of allergen solution (s) into your skin. You may experience mild to moderate itching or local discomfort at the sites of skin pricks with an allergen and the controls (positive and negative). You may experience some discomfort during and after a skin prick test, such as redness, pain, itching, burning, stinging, swelling or bruising. The symptoms are typically not bothersome. Usually, the hives resolve within 1 to 2 hours. In rare instances, study participants may have local swelling, which will completely clear within 2 to 3 days. Typically, the skin prick test procedure may cause you to experience some of your allergy symptoms. These symptoms may include sneezing, itchy eyes and tearing, runny nose and/or hives. Very rarely, some individuals with these types of symptoms

may develop a serious allergic reaction. Treatment with oral antihistamines is available during the study and is effective, although seldom required. Study staff will trace the slight bump (called a wheal) that forms on your arm as a reaction to the skin prick test on clear tape. This will be saved in your medical records as a measure of your allergic response. This is unlikely to cause any discomfort.

Rarely, a condition known as anaphylaxis may develop. This is a potentially life-threatening allergic reaction where breathing difficulties, hives, swelling of the skin or tongue, itchy skin, or decreased blood pressure can occur.

A study doctor/medical designee is always present, and medication/equipment for the treatment of anaphylactic reactions is available on-site throughout the study.

4.5 SPIROMETRY

Spirometry (lung function testing) requires you to breathe out forcefully into a tube. This may cause shortness of breath, light-headedness, or, in rare cases, fainting.

4.6 COVID-19 TEST

The risks associated with the COVID-19 nasal test are nasal discomfort which could include burning or stinging, watering eyes, runny nose, gagging, coughing, sneezing, headache and earache, which typically last no more than a few hours to a day. The risks associated with the COVID-19 throat swab are: coughing or gagging during the test.

4.7 REPRODUCTIVE RISKS

Female Participants:

If you are a woman who is pregnant, breastfeeding, or if you are planning on becoming pregnant, you must not take part in this study.

The effects of the study device on a fetus are currently not known. There may be risks to you and/or your child/unborn child of the study drug that are not known at this time. Females in this study may be of childbearing or non-childbearing potential.

You are considered a female of non-childbearing potential if you are naturally postmenopausal (no menses for at least 1 year), surgically sterile (bilateral tubal ligation (both tubes tied), bilateral oophorectomy (removal of both ovaries), hysterectomy (removal of uterus)), congenitally (present from birth) sterile, or diagnosed as infertile and are not undergoing treatment to reverse infertility.

If you are surgically sterile or surgically postmenopausal, you must have had the procedure (both tubes tied, both ovaries removed, or uterus removed) completed at least 3 months before Screening. You must provide documentation of the procedure at Screening. If documentation cannot be provided, you must agree to use a medically acceptable effective method of birth control.

If you are able to bear children, beginning from 1 month before Screening until 72 hours after the last study procedure, you must agree to remain abstinent or use 1 of the following effective methods of contraception:

- Condom and diaphragm with spermicide (foam, cream, gel, sponge)
- Condom and cervical cap with spermicide (foam, cream, gel, sponge)
- Oral, transdermal, injected or implanted hormonal contraceptive
- Hormonal or Non-hormonal intrauterine device (IUD)

If you are using your hormonal contraceptives, you must have been on the same hormonal contraceptive for at least one month before the Screening Visit and continue throughout the study.

A sterile partner is not considered an adequate method of birth control.

If you become pregnant or suspect you have become pregnant during the study, or within 30 days after the study has been completed, you must notify the Cliantha Research staff or study doctor immediately, and they will notify the Sponsor of the study. You will be asked to provide information regarding the pregnancy and its outcome.

4.8 Risk from using electronic Diary

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.

4.9 Unforeseen Risks

There may be additional risks to you while in this study that are not known at this time. If you experience any unusual side effects, please contact the study doctor immediately. You will be notified in a timely manner of any new information that may affect your participation or your willingness to continue your participation in this study.

5. STUDY RESTRICTIONS

The following table describes items that are restricted before and during this study. Participants who violate any of the above restrictions may be excluded or dropped from the study at the discretion of the study doctor.

Restricted Item	Start of Restriction	End of Restriction
Oral Steroids (Deltasone, Decadron etc.)	3 months before screening Visit 1	End of last study visit
SABAs (Acteril, Xopenex etc.)	8 hours before Screening Visit 1	End of last study visit
MABAs, ipratropium bromide, or ipratropium bromide with albuterol	24 hours before Screening Visit 1	End of last study visit
COVID-19 vaccine	3 days before each visit	End of each study visit
Cromolyn sodium	8 hours before Screening Visit 1	End of last study visit
Nedocromil	48 hours before Screening Visit 1	End of last study visit
Antihistamines (hydroxyzine, cetirizine, etc.)	3 days before Screening Visit 1	End of last study visit
LABAs (for example salmeterol, formoterol) or combination products containing bronchodilators (for example Symbicort)	Two weeks before Screening Visit 1	End of last study visit
Tiotropium	One week before Screening Visit 1	End of last study visit
Theophylline immediate release preparation	12 hours before Screening Visit 1	End of last study visit
Theophylline twice a day controlled-release preparation	24 hours before Screening Visit 1	End of last study visit
Theophylline once a day controlled-release preparation	36 hours before Screening Visit 1	End of last study visit
Caffeine/xanthine-containing products (coffee, tea, soft drinks, chocolate, energy drinks, etc.)	12 hours before each visit	End of each study visit

Intensive Exercise	At least 6 hours before each visit	End of each study visit
Beta-blockers, non-potassium sparing diuretics, digoxin, monoamine oxidase inhibitors, cholinesterase inhibitors or tricyclic anti-depressants	30 days before Screening Visit 1	End of last study visit
Leukotriene modifiers	7 days before Screening Visit 1	End of last study visit
Any surgery in the opinion of the study doctor would compromise the participant safety or integrity of the study data	3 months before Screening Visit 1	End of last study visit
Investigational drug/product	30 days before Screening Visit 1	End of last study visit
Smoking	At least 6 hours before each visit	End of each study visit

Please follow the table to ensure these restrictions are followed for the entire restriction period.

6. ALTERNATIVES TO PARTICIPATION

This is not a treatment study. Your alternative is not to participate in this study.

7. POSSIBLE BENEFITS

You are not expected to gain any direct benefit from taking part in this study, and your condition may worsen due to not being able to take anti-allergy treatments during the EEC. However, other allergy sufferers may benefit from what the Sponsor will learn in this study. You may benefit indirectly by learning about your health and medical conditions, including other allergies you have but do not know about. And you may find out for yourself whether the use of a medical device with a barrier function can reduce your allergy symptoms.

An indirect health benefit may be the information about your health status from the medical tests performed at screening and study.

8. COMPENSATION FOR PARTICIPATION

All tests, examinations, study treatments and medical care that are part of the study will be provided at no cost to you, your provincial health plan, or your private medical insurance (if any).

For completing this study in its entirety, you will be compensated a total of [redacted] CDN. Your full compensation will be given to you at the end of the study.

If you withdraw or are withdrawn from the study or do not complete the study in its entirety for any reason, you will be compensated on a pro-rated basis (compensation based on study visit completed). You may not be eligible for the entire amount. Please note that you will not be considered a study participant until you are dosed.

You will have [redacted] deducted from your compensation amount if you are late for any scheduled visit.

A significant part of our and your responsibility in the study is your health. As such, during your participation and/or after completion of the study, a study doctor may ask you to return to Cliantha Research for an unscheduled visit to follow up on any medical concerns such as changes to your health, abnormal lab results or vital signs. You may be required to have repeat blood tests or investigations (for example, physical exams and vital signs). You will be compensated [redacted] for any unscheduled visits.

If your compensation is deducted for any reason during the study, you may not receive the final compensation at the time when you would have otherwise been paid. Cliantha Research will ensure you receive your adjusted compensation no later than 1 week following the date when you would have originally received your compensation.

See below for compensation details:

[redacted]

*Eligible upon successful completion of Visit 1 and participation in Visit 2.

The study completion amount will only be given to participants who complete the study. If, for any reason, you are not able to attend all study visits and complete all study procedures, you will not receive the study completion amount.

9. PRIVACY AND CONFIDENTIALITY

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 medical, health and personal information collected during the study will be handled by qualified, trained and designated staff members. Privacy and confidentiality will be maintained and governed

by company policy in compliance with the Canadian Personal Information Protection and Electronic Documentation Act (PIPEDA) and the Ontario Personal Health Information Protection Act (PHIPA). Your personal and medical information will not be disclosed unless required by law.

All health and medical records, and other information collected during the study will be identified by a unique study number assigned to each participant and their two or three letter initials. Your personal or health information will not be recognizable by anyone outside the study site. Your name and identification will not appear on study records. The study Sponsor (or their representatives), Advarra (an ethics committee that reviews the ethical aspects of clinical studies and is responsible for the protection of rights of human participants), and government regulatory agencies (such as Health Canada and the US Food and Drug Administration [FDA]) will be allowed access to study records at the study site if they ask. This inspection is to check the accuracy of study records. The data from this study may also be submitted by the Sponsor to government agencies and/or published, but your identity will not be disclosed.

You have the right to ask the study doctor about the data being collected for the study and about the purpose of these data. You have the right to ask the study doctor to allow you to see your personal information and, if needed, to request to have corrections made. If you have any questions about PHIPA or PIPEDA, please contact the study site.

For security purposes, video cameras are located throughout the public areas of the study clinic. All images recorded are only available to Cliantha Research staff and are not released to anyone else unless required by local regulatory authorities.

By signing and dating this consent form, you are authorizing access to your medical records. All medical records will be retained at the study site for 25 years, as required by laws governing clinical research studies. You are also giving permission to the study doctor to provide direct/remote access to your data, including the health information with the Sponsor drug company for this study (Altamira Medica) and auditors associated with the Sponsor, IRB and the regulatory agencies. In addition, study medical records and data may be given to the ethics review board, Advarra and government regulatory agencies including Health Canada, FDA (United States), EMA (European Union), or other foreign regulatory agencies in order to obtain approval to market the Sponsor's product.

Your personal information will be redacted prior to sharing it with the monitors remotely.

If you choose to participate in future clinical studies at Cliantha Research, the medical screening information obtained for this study may be used to verify your medical history. The persons who would have access to this information will be specified in the study-specific consent form for any future studies.

You cannot participate in this study unless you allow your personal health information to be used by the study staff. Your signature on this form permits the study staff to use your health information as described here.

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.

10. IN CASE OF AN INJURY RELATED TO THIS RESEARCH

If you experience an injury or illness as a result of your participation in the study, the necessary medical treatment will be available at no additional cost to you. This will be covered by either Cliantha Research, the Sponsor or your medical plan, as the case may be. By signing and dating this consent form, you are not releasing the study doctor(s), Institution(s), and/or Sponsor(s) from any of their legal or professional responsibilities.

11. LEGAL RIGHTS

You do not lose any legal rights by signing this consent form, including, but not limited to, your right at law to claim compensation for injury where you can prove negligence.

If you have received the study device in any period, approval of the study doctor must be obtained before your release from the study site. You will not be prevented from leaving the site should you ask to do so; however, you will be asked to sign a waiver releasing Cliantha Research from responsibility for events that are the direct result of leaving without examination by a study doctor.

12. WHOM TO CONTACT FOR MORE INFORMATION

If you have any questions about this research study or your study visits, to report a research-related injury or for information about the procedures, you may contact the Study Coordinator or any member of study staff at the phone numbers listed below:

[redacted]rs (9:00 am to 5:00 pm), Monday to Friday.

[redacted]for after-hours contact.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have concerns or questions about your

rights as a research participant, please contact your family physician and/or lawyer or contact the IRB:

- By **mail**:
- or call **toll free**:
- or by **email**:

[redacted]

Please reference the following number when contacting the Study Subject Adviser: Pro00057602.

Please note that Advarra does not mediate compensation issues between study participants and facilities. All queries regarding study payments should be directed to Cliantha Research.

For medical emergencies outside of Cliantha facility, please call 911.

13. VOLUNTARY PARTICIPATION/WITHDRAWAL FROM THE STUDY

Your participation in this study is entirely voluntary. You do not have to participate, or you may choose to withdraw at any time without penalty or loss of benefits to which you are otherwise entitled. If you decide to stop participating at any time during the study, just let the study doctor or study staff know as soon as possible.

The study doctor may also choose to discontinue your participation in the study for the following reasons:

- If you develop a medical condition that may interfere with the study results
- If you develop a medical condition that may put you at risk
- If you do not follow study procedures or comply with study restrictions.

In addition to the study doctor, the following people and agencies can stop your participation in the study:

- Health Canada
- The study sponsor
- Other regulatory agencies (for example, FDA, EMA).

If you decide to leave the study early, or if you are withdrawn from the study, you will be asked to undergo the tests that would have been done at the last visit of the study.

CONSENT

I confirm that I have been given sufficient time to consider all the information given to me and ask questions. In addition, I confirm that, to the best of my knowledge and belief, all technical language used by the study staff has been explained and that I have received satisfactory answers to all questions that I

have asked. I have read all of the pages of this informed consent document, to the best of my knowledge and belief, understand the consent form, and voluntarily agree to participate in this research study. I am aware that I will receive a copy of this signed and dated consent.

PRIMARY HEALTH CARE PROVIDER NOTIFICATION OPTION

I consent to have my family doctor or primary health care provider notified by the study site of my participation in this study and/or any significant findings related to my health (please check yes or no).

☐ **YES** (If yes, please complete the information below)
☐ **NO**

Name and address of family doctor or primary health care provider:	Name: Address:
Telephone and Fax Number:	Tel: Fax:

Name of Study Participant (PRINT)	Signature	Date

Name of Person Obtaining Consent (PRINT)	Signature	Date