

PARTICIPANT INFORMATION AND CONSENT FORM

Sponsor / Study Title: Ethical Naturals Inc. / “A randomized, triple-blind, placebo controlled, cross-over clinical trial to assess the efficacy of a single dose of AlphaWave® L-Theanine on cognitive function in healthy adults with moderate stress”

Protocol Number: 25ENCCA02

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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

Prolonged periods of stress can lead to negative health consequences. There are many ways to help reduce stress, such as exercising, quitting smoking, practicing deep breathing, or trying meditation. However, these methods often require long-term commitment and regular practice to be effective. Taking natural health products to help reduce stress may be a sustainable solution. Therefore, exploring alternative, more sustainable, and natural health methods may be beneficial.

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L-theanine is an amino acid found mainly in green tea leaves and is known for its calming effects. An amino acid is a natural substance your body uses to build proteins, which helps your body stay healthy and work properly. AlphaWave® L-Theanine, is a dietary supplement containing 200 mg of L-theanine per capsule. Previous studies suggest that L-theanine may improve stress and cognitive function, but more research needs to be done. Therefore, the purpose of this study is to assess the effects of a single dose of AlphaWave® L-Theanine on cognitive function and stress relief in healthy adults with moderate stress.

Study Population

This study will include approximately 40 healthy males and females between 18-60 years old with moderate stress.

How Long Is The Study?

If eligible after the screening visit, your participation in this study will last approximately 8 days.

Important Things To Note

- To determine your eligibility to participate in this study, detailed information about your lifestyle, medications, and medical history will be collected. This information will help determine if you meet the necessary inclusion and exclusion criteria for this study.
- By signing this consent form, you are not guaranteed to be enrolled in the study. Your participation depends on meeting the study's specific eligibility criteria, which will be determined through a series of questions and assessments.
- This study uses competitive enrollment. This means that once 40 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.
- You should not participate in the study if your current job requires rotating shifts that could disturb your normal sleep-wake cycle.
- If you voluntarily agree to participate in this study, you must be willing to:
 - Come to your scheduled visits at about the same time each visit, between 10:30 and 11:30 in the morning.
 - Eat breakfast by 9:00 a.m. before coming to the clinic for Visit 2 and 3, and only drink water after you've finished your breakfast (no food or other drinks allowed)
 - Avoid caffeine (e.g., tea, coffee, energy drinks) for 12 hours prior to your visit 2 and visit 3
 - Avoid alcohol and vigorous physical activity for 24 hours prior to your visit 2 and visit 3
 - Avoid certain anti-allergy medications for 48 hours prior to your visit 2 and visit 3, your study staff can tell you more about which anti-allergy medications should be avoided
 - Collect urine samples for pregnancy tests (if applicable)
 - Provide saliva samples at visit 2 and visit 3
 - Complete questionnaires, records, and diaries associated with the study and complete all study visits
 - Maintain current lifestyle habits (such as diet, physical activity, medications, supplements, and sleep) throughout the study

THIS IS AN IMPORTANT DOCUMENT – KEEP FOR FUTURE REFERENCE**Study Design**

The study design describes the overall plan for how the study is conducted. This is a *randomized, triple-blind, placebo controlled, cross-over* study.

- **Randomized** — During Visit 2, if you are eligible to participate, you will be randomly assigned by chance (like flipping a coin) to 1 of 2 study groups:
 - One group will receive **AlphaWave® L-Theanine** at **Visit 2** and a **placebo** at **Visit 3**.
 - The other group will receive a **placebo** at **Visit 2** and **AlphaWave® L-Theanine** at **Visit 3**.

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

- **Triple-blind** — Neither you, the study staff, nor the researchers analyzing the data will know which group you have been assigned to. However, if needed for your safety, the study staff can find out this information.
- **Placebo controlled** — A placebo is an inactive substance that looks like the **AlphaWave® L-Theanine** capsules but has no active/natural health product ingredients. It is used to help determine whether **AlphaWave® L-Theanine** has real effects beyond what might happen by chance or expectation.
- **Crossover** — You will start the study by receiving one product (either **AlphaWave® L-Theanine** or placebo) at Visit 2 and then switch to receive the other product at Visit 3. There will be a **washout period** between Visit 2 and Visit 3 (Day 1 to 8 + 2 days). This washout period allows time for the first product to clear from the body before you begin the second one. The crossover study design allows researchers to compare the effects of both products within the same person.

What Will Happen During The Study?

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

Assessments and Procedures

PERCEIVED STRESS SCALE (PSS) (Visit 1, 2 and 3) – This questionnaire will be used to measure how stressed you feel.

COMPUTERIZED MENTAL PERFORMANCE ASSESSMENT SYSTEM (COMPASS) (Visit 2 and 3) – This program will be used to assess your cognitive function which includes attention; episodic, spatial and working memory; psychomotor, processing and motor speed; and reaction time assessments. You will complete a familiarization assessment during Visit 1 referred to as **Cognitive Demand Battery Test (CDB)**.

GO/NO-GO ASSESSMENT (Visit 2 and 3) – This is a computer-based test that measures your ability to stay focused and control your responses (self-control).

URINE SAMPLES (Visit 1, 2 and 3) – 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.

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SALIVA SAMPLES (Visit 2 and 3) – You will collect saliva samples for the analysis of cortisol using the passive drool method (a method of collecting saliva samples by allowing saliva to naturally pool at the bottom of your mouth). You will be provided with a collection container and instructed on how to provide the sample.

STANDARDIZED MEAL – You will consume identical meals—including the same portions—at Visit 2 and 3 comprised of the following options:

- Tomato soup and crackers
- Turkey and Swiss cheese OR Roasted vegetable and Swiss cheese sandwich on whole wheat bread
- Apple with peanut butter

No herbal decaffeinated tea, decaffeinated coffee, or juices will be allowed. However, water will be provided.

STUDY DIARY – You will complete an online daily study diary throughout the study. Questions about lifestyle habits and any changes in medications and/or health will be included.

Schedule of Study Visits

The following chart outlines the assessments to be conducted at each visit, along with the requirements to be followed beforehand.

Visit 1 (Screening) <i>Some portions of this visit may occur virtually</i>
<p>After informed consent is obtained, visit assessments will include:</p> <ul style="list-style-type: none"> • Review of your medical history, medications, and current health status • Completion of the Perceived Stress Scale • Urine pregnancy test (If applicable) • Seated blood pressure and heart rate measurements • Weight and height measurements (used to calculate Body Mass Index or BMI) • Completion of the familiarization CDB assessment • Potential eligibility to participate in the study will be reviewed
Visit 2 (Day 1) and Visit 3 (Day 8 + 2 days)
<p>Before your study visits, you will be required to:</p> <ul style="list-style-type: none"> o Avoid caffeine (for example, tea, coffee, energy drinks) for 12 hours o Avoid alcohol and vigorous physical activity for 24 hours o Avoid certain anti-allergy medications, called first generation anti-allergy medications for 48 hours. Examples include Benadryl [diphenhydramine], Atarax [hydroxyzine], Gravol [dimenhydrinate]. <p>You will return to the clinic in accordance with the pre-visit instructions and after eating breakfast by 9:00 a.m. You will avoid eating or drinking anything (except water) between breakfast and your clinic visit. Visit assessments will include:</p> <ul style="list-style-type: none"> • Review any changes in health and medications

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- Urine pregnancy test (If applicable)
- Seated blood pressure and heart rate measurements
- Weight measurement (BMI calculation)
- Return and review of study diaries (*only at Visit 3*)

During Visit 2 – If you still meet all necessary study criteria and are eligible, you will be randomized and enrolled in the study.

During Visits 2 and 3, you will complete the following assessments and procedures **before** and **after** taking the study product:

BEFORE TAKING THE STUDY PRODUCT:

- **About 2 hours before** – You will eat a standardized meal provided by the study staff
- **About 1 hour before** – You will provide a saliva sample (before assessments)
- **Right after the saliva sample** – You will complete the following assessments:
 - COMPASS starting with the CDB
 - PSS
 - Go/No-Go Assessment

You will then take one capsule (of either AlphaWave® L-Theanine or placebo) with a glass of room-temperature water, under study staff supervision. Any changes in health will be reviewed before and after study product consumption.

AFTER TAKING THE STUDY PRODUCT:

- **About 1 hour after** – You will give another saliva sample (before assessments)
- **Right after the saliva sample** – You will complete the following assessments:
 - COMPASS starting with the CDB
 - PSS
 - Go/No-Go Assessment
- You will give another saliva sample (after assessments)
- Study diaries and all instructions will be dispensed (*only at Visit 2*)

WASHOUT PERIOD (Day 1 to Day 7 [+3 days]) – Between Visit 2 and Visit 3 you will complete a washout period of a minimum of 7 days, and you will report any changes in medications and/or health in the daily study diaries. You will not take any study product during this time.

Medications, Supplements, And Food/Drinks

If you are taking any prescribed medications, you must agree to maintain your dosing regimen during the study, unless otherwise recommended by your general physician/nurse practitioner. If they recommend any medication or dose changes, notify the study staff immediately. Do not stop any regular prescribed medications unless instructed by your healthcare provider. Stopping medication without medical advice may harm your health. If you stop or change any medications or dosages, inform the study staff right away.

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- If you are taking prescribed medications or treatments that could affect the study results, you may only be considered for participation if your healthcare provider discontinues them. The study doctor will recommend an appropriate washout period prior to enrollment in the study.
- If you use any over-the-counter medications, supplements, foods and/or drinks that could affect the study results, 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 prior to enrollment: 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 urine pregnancy test at Visit 1, Visit 2, and Visit 3, 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 completion of your pregnancy, collect information about your pregnancy, its outcome, and the health of your child (as applicable).

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

AlphaWave® L-Theanine and the placebo will be in capsule form.

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Medicinal Ingredient	Quantity
AlphaWave® L-Theanine	200 mg

Non-medicinal ingredients: microcrystalline cellulose, hydroxypropyl methyl cellulose, stearic acid, silicon dioxide

Placebo Ingredients: microcrystalline cellulose, hydroxypropyl methyl cellulose

Directions:

- If eligible, during Visit 2 and Visit 3, study staff will provide you with one capsule of either AlphaWave® L-Theanine or placebo
- You will consume the product in front of the study staff with 250 ml of room temperature water
- 100% of study product consumption is required to continue in the study

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

- Sleep disturbances, Drowsiness, Weakness/fatigue
- Irritability, Trouble concentrating
- Gastrointestinal discomfort, Metallic taste, Dry mouth

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

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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-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 doctor or study staff and without penalty or loss of benefits to which you are otherwise entitled.
- You may be asked to undergo some final visit procedures. These may include returning to the clinic for any end-of-study assessments or questionnaires.
- If the study doctor or study staff finds out any related information that may greatly affect your well-being (for example, information related to your health), they will share it with you immediately.

The Sponsor has the right to stop the study at any time.

The study doctor may also stop your participation in the study at any time without your consent, but you will be informed about the reason. Reasons for this may include, but are not limited to:

- Missing scheduled study visits
- Not taking study product as directed
- Not completing required assessments or procedures
- Development of medical conditions or serious side-effects that may pose a health risk to you or the study outcomes
- The need for restricted medication(s) during the study
- If you become pregnant during the study

New Findings

Any significant findings that become available during the study which may influence your continued participation in the study will be disclosed to you as soon as possible.

Benefits

While there may be no immediate benefit to you, the results of this study will provide some of the required scientific evidence for the study products in this clinical research study. Your participation in this study supports the research that is required to ensure the science behind the study products.

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- 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 \$400 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 2 and received study product), the compensation breakdown is as follows:

- Visit 1 (Screening): \$0
- Visit 2: \$150
- Visit 3: \$250

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 may be requested to complete some safety assessments and visit procedures if you consent to doing so. If you complete the early termination visit, you will be compensated \$50.

You may also be eligible for coverage on transportation costs (i.e. bus tickets, parking tickets).

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.

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

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

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

Future Use Of Data And Specimens

- Your personal information and/or biospecimens collected during this study may be stored and used for future research. If so, any personal identifiers will be removed so that the information or samples cannot be linked back to you. As a result, we will no longer be able to identify them or identify you.
- Study doctors, including study doctors from collaborating institutions, can request this data and samples for new research. Samples and data may also be shared with outside non-profit academic study doctors as well as with for-profit study doctors or commercial entities, with whom we collaborate.
- You will not be asked to provide additional informed consent for the use of your de-identified information or samples in future research.
- Future 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.

Future Contact

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

Whom To Contact About This Study

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

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

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

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

THIS IS AN IMPORTANT DOCUMENT – KEEP FOR FUTURE REFERENCE**Voluntary Consent To Participate**

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

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

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

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

Signature of Participant

Date (MMM,DD,YYYY)

Time (HH:MM) AM/PM

FOR PERSON EXPLAINING CONSENT

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

Printed Name of Person Explaining Consent

Signature of Person Explaining Consent

Date (MMM,DD,YYYY)

Time (HH:MM) AM/PM



THIS IS AN IMPORTANT DOCUMENT – KEEP FOR FUTURE REFERENCE**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

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