PARTICIPANT INFORMATION AND CONSENT FORM

Sponsor / Study Title:	**Unigen Inc.**
	"A randomized, triple-blind, placebo controlled, parallel clinical trial to investigate the safety and efficacy of Maizinol™ on sleep quality in a healthy population with difficulty falling asleep or staying asleep."
Protocol Number:	**22UNRCZ01**
Principal Investigator (Study Doctor):	**David Crowley, MD**
Telephone:	**519-438-9374**
Address:	**KGK Science Inc.** **275 Dundas St, Suite G02** **London, ON N6B 3L1**

You are being asked to participate in a clinical research study. Your participation in this study is strictly voluntary. To decide whether you want to be part of this research, you should understand the potential study risks and benefits to make an informed decision. This process is known as informed consent. This consent form describes the purpose, procedures, possible benefits, and risks of the study. This form will also describe how your personal information will be used. Please read this document carefully and do not hesitate to ask any questions you may have regarding the information given and the study. The study doctor and study staff will answer all questions you may have.

Once you understand the study, you will be asked to initial each page as well as sign and date the last page of this form to participate. You may have a copy of this form in advance of signing and dating to review at your leisure or to ask advice from others.

PURPOSE OF THE STUDY

Sleep disturbances, such as difficulty falling asleep or difficulty staying asleep, is reported to affect approximately 25 to 33% of the American population. This percentage is estimated to have increased to as much as 40% during the COVID-19 pandemic. Many sufferers have turned to prescription sleep aids, however, long-term users may experience adverse side-effects such as diarrhea, confusion, memory impairment and fatigue. Natural, complimentary, and alternative sleep aids may provide a safer and more effective relief of sleep disturbances in healthy people.

The purpose of this study is to evaluate the safety and efficacy of Maizinol™, an investigational extract derived from corn plant leaves, on sleep quality in a healthy population with difficulty falling asleep and/or staying asleep after a 28-day supplementation period. "Investigational" means that Maizinol™ has not been approved by Health Canada for use outside of research studies like this one.

THIS IS AN IMPORTANT DOCUMENT – KEEP FOR FUTURE REFERENCE

Participant Initials: _____

HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY

- If you are eligible after the screening visit, your participation in this study is approximately 28 days.
- There may be a need for a washout period prior to beginning the study, if you are taking any restricted medications, natural products, foods or participating in restricted activities that will conflict with this study.
- You will have a total of 4 in-clinic visits (Screening, Day 0, Day 14, and Day 28). The first visit is a screening to assess if you are eligible to participate.
- You will also receive telephone compliance calls on Days 7 and 21.
- We are looking for 80 healthy adults with difficulty falling and/or staying asleep.

WHAT WILL HAPPEN DURING THE STUDY?

Before the study starts, you will be asked to sign and date this Participant Information and Consent Form. You will be asked to read the information for this study and will be given the opportunity to seek more information if needed. You have the option to keep this form to review before making your decision. If agreeable, you will initial, sign and date the consent form and receive a duplicate copy. Once consent has been obtained, the screening visit will proceed. The table below lists the events, requirements, and procedures for each visit of the study including the initial screening visit. It also lists any items that are of importance following each visit.

You are going to be asked not to consume anything other than water within two hours of your baseline and subsequent visits.

If you have any questions about any aspect of the study, please ask a member of the study staff.

SCREENING DAY -45 TO -8	RUN-IN DAY -7 TO -1	VISIT 2, DAY 0 BASELINE	VISIT 3 DAY 14	VISIT 4 DAY 28
Requirements for the Visit				
Be prepared to discuss medical history, current health status, current medications, and natural health products you are taking.	Please ensure you complete your study diary. Remember not to consume anything other than water for two hours prior to your next visit.	Collect 2 saliva samples within 30 minutes of waking the morning of this visit. Be prepared to review current health status, medications, and natural health products you are taking. Remember not to consume anything other than water for two hours prior to your next visit.	Collect 2 saliva samples within 30 minutes of waking the morning of this visit. Be prepared to review your current health status, medications, and natural health products you are taking as well as your current health status. Remember not to consume anything other than water for two hours prior to your next visit. This visit will need to occur at the same time as visit 2.	Collect 2 saliva samples within 30 minutes of waking the morning of this visit. Be prepared to review your current health status, medications, and natural health products you are taking as well as your current health status. This visit will need to occur at the same time as visit 2 and 3.
Visit Events				
Informed Consent for participation in the study is obtained. If consent provided, eligibility for study reviewed. Record any adverse events.	We will dispense your actigraphy and Electroencephalogram (EEG) device (device which records, monitors, displays and stores your biophysical sleep parameters) and will explain to you how to use it.	Review inclusion/exclusion criteria. Enrollment and randomization into study. Record any adverse events.	We will collect your saliva samples and completed study diaries. We will dispense new diaries and a new saliva collection kit. You will return your EEG and actigraphy device to review	We will collect your saliva samples and completed study diaries. You will return your EEG and actigraphy device to review the readings.

SCREENING DAY -45 TO -8	RUN-IN DAY -7 TO -1	VISIT 2, DAY 0 BASELINE	VISIT 3 DAY 14	VISIT 4 DAY 28
We will collect information on sleep habits, reasons for difficulty falling/staying asleep. We will dispense your study diary and explain the run-in period to you. We will dispense your saliva kit and explain how to collect your sample.	We will dispense a urine collection kit.	We will collect your saliva samples and completed study diaries. We will dispense new diaries and a new saliva collection kit. You will return your EEG and actigraphy device to review the readings and will take EEG home with you again. We will dispense your study product and teach you how to take it. We will collect your urine sample and will dispense a urine collection kit.	the readings and will take EEG home with you again. You will return your unused study product and remnants so we can calculate your compliance. We will dispense the new study product. You will receive a telephone call in one week (Day 21). Record any adverse events. We will collect your urine sample and will dispense a urine collection kit.	You will return your unused study product and remnants so we can calculate your compliance. Record any adverse events. We will collect your urine sample.

SCREENING DAY -45 TO -8	RUN-IN DAY -7 TO -1	VISIT 2, DAY 0 BASELINE	VISIT 3 DAY 14	VISIT 4 DAY 28
Procedures at Visit				
Urine pregnancy test for females of child-bearing potential. Seated resting blood pressure and heart rate measurements will be taken. We will take a blood sample to ensure you are healthy.		Urine pregnancy test for females of child-bearing potential. We will collect a urine sample for analysis of study outcomes. We will measure your heart rate and blood pressure. We will collect a blood sample to measure serotonin, melatonin, and GABA (gamma aminobutyric acid) and future exploratory outcomes. We will administer the Pittsburgh Sleep Quality Index (PSQI), PERCEIVED STRESS SCALE (PSS), COVID-19 QOL (Quality of Life), and the Profile Of Mood States (POMS) questionnaires.	We will measure your heart rate and blood pressure. We will collect a urine sample for analysis of study outcomes. We will collect a blood sample to measure serotonin, melatonin, and GABA and future exploratory outcomes. We will administer the PSQI, PSS, COVID-19 QOL, and the POMS questionnaires.	Urine pregnancy test for females of child-bearing potential. We will collect a urine sample for analysis of study outcomes. We will measure your heart rate and blood pressure. We will collect a blood sample to measure serotonin, melatonin, and GABA and future exploratory outcomes and to ensure you are healthy. We will administer the PSQI, PSS, COVID-19 QOL, and the POMS questionnaires.

Important Items to Note

RANDOMIZATION TO STUDY GROUP: If eligible, you will be enrolled into the study and will be randomized into 1 of 2 groups:

- Maizinol™
- Placebo (inactive substance)

Randomized means that you will be assigned by chance (like drawing numbers from a hat) to a study group. This is a triple-blind study, so neither you, the study doctor nor the person analyzing the data will know which group you have been randomized to. We will dispense study products based on randomization. Our study staff will instruct you how to take the study products and fill out study diaries. You have an equal (1 in 2) chance of being in either of the study groups. Neither you nor the study doctor will be able to pick which group you are in, but the study doctor can find out if it is necessary to know for your health. For further information on the study product's ingredients and directions, see the "Study Product Ingredients" section.

BIOMETRIC MEASUREMENTS: Study staff will take biometric measurements including seated, resting blood pressure and heart rate.

BLOOD COLLECTION: At your screening visit, blood will be collected to verify that you are healthy before being enrolled in the study. This is done by sterilizing the skin on your arm, then inserting a sterile needle and drawing the blood, then removing the needle. On days 0, 14 and 28 another blood draw is required.

URINE SAMPLES: Females of child-bearing potential will be required to provide a urine sample at Screening, Day 0 and Day 28 for a urine pregnancy test. You will be provided with a collection container and instructed on how to provide the sample. All participants will be asked to collect their first morning urine for future analysis.

SALIVA SAMPLES: You will be asked to collect 2 saliva samples within 30 minutes of waking the morning of your in-clinic visits. Please do not eat or drink anything for at least 30 minutes and do not brush your teeth before taking your samples.

ACTIGRAPHY AND EEG DEVICE: This is a device you will use at home to record, monitor, display and store your biophysical sleep parameters. You will wear this device while you sleep on the dates the study staff provide to you.

***IMPORTANT**: You will be dispensed this equipment to take home with you to monitor your sleep. You are responsible for returning the equipment, in its original working condition, to the clinic upon exiting the study. Failure to do so may result in you being held responsible for the replacement cost of the equipment if you were at fault in any way for breaking it.

PITTSBURGH SLEEP QUALITY INDEX (PSQI): This is a self-reported questionnaire that assesses sleep quality.

PERCEIVED STRESS SCALE (PSS): This is a 10-item tool commonly used to assess stress in research. It measures the degree to which situations in one's life are considered stressful.

COVID-19 QUALITY OF LIFE (QoL) QUESTIONNAIRE: This is a 6-item questionnaire used to assess the impact of COVID-19 on your quality of life.

PROFILE OF MOOD STATES (POMS): This is a questionnaire used to measure mood states.

To be enrolled into the study, YOU WILL NEED TO:

- Be between 18 and 65 years of age, inclusive, at screening.
- If you are a female who is not of child-bearing potential, you must have undergone a sterilization procedure (for example, hysterectomy, bilateral oophorectomy, bilateral tubal ligation, complete endometrial ablation) or have been post-menopausal for at least 1 year prior to screening.

  OR

  If you are a female of child-bearing potential and have a negative baseline urine pregnancy test, you must agree to use a medically approved method of birth control for the duration of the study. All hormonal birth control must have been in use for a minimum of three months. Acceptable 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.
  - Non-heterosexual lifestyle or agrees to use contraception if planning on changing to heterosexual partner(s).
  - Vasectomy of partner at least 6 months prior to screening.
- Have self-reported difficulty falling asleep (taking longer than 30 minutes to fall asleep) or staying asleep, with two or more difficulty falling/staying asleep episodes in a 7-day period for at least one month.
- Agree to maintain your lifestyle, as much as possible, throughout the run-in and study period including the following: diet, medications, supplements, and exercise. Agree not to start taking any new supplements.
- Agree to stay in the current time zone for the duration of the run-in and study period.
- Agree to refrain from drinking herbal tea that affects sleep within 2 hours of bedtime unless this is your usual routine and you do not change this routine for the duration of the study.
- Agree to avoid caffeine or other stimulants (that is, energy drinks) after 3:00 pm for the duration of the run-in and study.
- Be willing to provide information on COVID-19 infection and vaccination history.

To be enrolled into the study, YOU CANNOT have the following medical conditions/lifestyles:

- Be a woman who is pregnant, breastfeeding, or planning to become pregnant during the study
- Have an allergy, sensitivity, or intolerance to the study products' active or inactive ingredients
- Have previously been diagnosed with a sleep disorder or use a continuous positive airway pressure -machine (CPAP)

- Be a menopausal woman currently experiencing hot flashes
- Currently be employed in a position that requires shift work, or have worked shift work in the past 3 weeks
- Travelled across one or more time zones in the two weeks prior to run-in
- Currently be experiencing vivid nightmares or sleepwalking
- Have an unstable metabolic disease or condition known to disrupt sleep, as assessed by the study doctor
- Currently have or had a history of any significant psychiatric conditions, as assessed by the study doctor
- Had a significant cardiovascular event in the past 6 months. If you have had no cardiovascular event, and have been on a stable dose of medication for 3 months, you will be assessed by the study doctor on a case-by-case basis
- Have unstable high blood pressure. Treatment on a stable dose of medication for at least three months will be considered by the study doctor
- Have Type I Diabetes or Type II Diabetes with an HbA1C of ≥ 7.5%
- Self-reported current thyroid disorder or history of a thyroid disorder. Treatment on a stable dose of medication for at least 3 months will be assessed by the study doctor on a case-by-case basis
- Had major surgery in the past 3 months or have surgery planned during the study. Minor surgery will be considered on a case-by-case basis by the study doctor
- Have or have had cancer, except skin basal cell carcinoma completely excised with no chemotherapy or radiation with a follow up that is negative. If you have been in remission for more than 5 years after diagnosis, that is acceptable
- Have an auto-immune disease or are immune compromised
- Have a positive diagnosis for Hepatitis B, C or HIV
- Currently be using any prescription or over-the-counter medications, supplements, foods, or drinks that may interfere with the efficacy and/or safety of the study product
- Use medical cannabinoid products
- Chronically use cannabinoid products (>2 times per week). Occasional users (≤2 times per week) may participate if they agree to stop use for the duration of the run-in and study period, as assessed by the study doctor
- Use tobacco products within 90 days of baseline, as assessed by the study doctor
- Drink more than 2 standard alcoholic drinks per day, on 3 or more days per week, as assessed by the study doctor
- Have abused alcohol or drugs within the past 12 months
- Used illicit drugs in the past 6 months, as assessed by the study doctor
- Habitually consume excess caffeine (>500 mg/day)
- Donated blood within 30 days prior to baseline, during the study, or plan to donate blood within 30 days of your last study visit
- Participated in another clinical research study within 30 days of baseline, as assessed by the study doctor

To be enrolled into the study, YOU CANNOT consume the following prescribed medications (if you have been prescribed these medications, you may only be assessed for eligibility for this study if your family physician has now taken you off the following medications):

- Benzodiazepines
- Prescription medications used for the treatment of sleep disorders (for example, Zopiclone, Zaleplon, Zolpidem, Ramelteon, etc.)
- Antidepressants, anxiolytics, and narcotics
- Stimulants (for example, methylphenidate, modafinil, etc.)

If you are taking any prescribed medications, you must agree to maintain your dosing regimen during the study, unless otherwise recommended by your regular doctor. If your regular doctor recommends any medication changes, please notify the study staff.

To be enrolled into the study, YOU CANNOT consume the following health products/supplements, over-the-counter medications, and food/drinks and must stop taking them for the length of time indicated before being enrolled in the study and agree to not consume them during the study:

- Supplements containing corn leaf extract
- OTC (over the counter) medications and/or supplements marketed to promote sleep (for example, melatonin, valerian root, passionflower, 5 HTP, Ashwagandha, magnolia extracts, etc.) (7 days)
- Anti-allergy medications and other medications containing sleep aids (non-drowsy allergy medications are allowed) (7 days)

Please be prepared to discuss all prescription and over-the-counter medications (including vitamins, nutritional supplements, "natural" remedies, homeopathic medicine, and herbal preparations) and functional foods (that is, probiotic containing foods, high fiber foods) you use with your study doctor.

Birth control, pregnancy, and breastfeeding

You must not participate if you are pregnant, breastfeeding or planning to become pregnant during the study.

Females able to become pregnant (not post-menopausal, have had a menstrual period in the past 1 year, or has not had any of the following surgeries: hysterectomy, bilateral oophorectomy, complete endometrial ablation, or bilateral tubal ligation) must agree to a urine pregnancy test and must be using an approved method of birth control during the study. If using hormonal birth control, you must have been using it for at least 3 months. 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
- Non-heterosexual lifestyle or agrees to use contraception if planning on changing to heterosexual partner(s)

- Vasectomy of partner at least 6 months prior to screening

The study staff will discuss these contraceptive methods with you.

If you become pregnant during the study, you must stop taking the study products immediately and contact the study doctor. The study doctor will follow up with you until the child's birth and 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 or your female partner become pregnant.

STUDY PRODUCT INGREDIENTS:

Study Product: Maizinol™

Dietary Ingredient	Quantity
Corn Leaf Extract	500 mg

Non-medicinal ingredients: gelatin, titanium dioxide, brilliant blue FCF sodium salt, Allura red AC

Placebo
Non-medicinal ingredients: Microcrystalline cellulose MCC

DIRECTIONS

Please take one capsule of study product per day, 60 minutes before bedtime, starting on Day 0. Please save all open and unopened packages and return them to the clinic at each of your visits so we can calculate your compliance. If you miss a dose one night, please document that you missed the dose in your diary and continue with your normal dose the next night. Do not take more than one capsule per day.

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. For your safety, you must discuss your current medical care with the study doctor or study staff, as well as changes in medical conditions during the study. In addition, all new medications that are taken during the study should be reported to the study staff.

The study products are intended for your use only as the study participant. They should not be given to anyone else or left in a place where a small child or a pet could accidentally swallow it. All packaging and unused study products are to be returned to the study staff.

ALTERNATIVE TREATMENTS

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

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 investigational product.

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 signs of an allergic reaction that could be a sign of a life-threatening (anaphylaxis) include:

- rash
- difficulty breathing
- wheezing
- sudden drop in blood pressure (making you feel dizzy or lightheaded)
- swelling around the mouth, throat, or eyes
- fast pulse
- sweating

You should get medical help or go to the emergency room, and contact the study doctor or study staff, if you have any of the above-listed effects or any other side effects during the study. Please also refer to section "Whom to Contact About This Study" for instructions on what to do in case of an emergency.

Ask the study doctor or study staff if you have questions about the signs or symptoms of any side effects you read about in this consent form.

Please tell the study doctor or study staff right away if you experience any side-effects, problems with your health or the way you feel during the study, whether you think these problems are related to the study products or not.

While getting used to wearing the actigraphy device while you sleep, you may experience some minor physical inconveniences, such as disrupted sleep.

If I stop taking my regular medication, what are the risks? You should not stop your regular medication unless your regular doctor has informed you to do so. If you stop your regular medication to be in the study, your health might worsen. Please tell the study doctor or study staff right away if you have stopped taking your regular medication.

What are the risks from blood collection? Blood samples will be drawn from a vein (typically in the arm) with a sterile needle. You may experience some discomfort when the blood is drawn, and you may have some bruising afterwards as well. There is a minimal risk of infection in blood collection. Fainting during a blood draw can occur, though it is not common. Please advise the study staff if you normally faint with blood draws.

If the results of any blood test are abnormal, the study doctor may request that you have an additional blood sample drawn to repeat the test.

During this study, the maximum amount of blood expected to be drawn is approximately 115 mL for females (approximately 7.5 tablespoons) and 130 mL (approximately 8.5 tablespoons) for males. The maximum amount of blood drawn at any single visit will not be more than 45 mL (approximately 3 tablespoons) for females and 50mL (approximately 3 tablespoons) for males.

Potential risks from eConsent You will be emailed a PDF copy of this signed and dated 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

- You are free to choose to stop participating in the study at any time 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 and study products 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, as well as an exit questionnaire. If the study doctor or study staff finds out any non-study related information that may affect your well-being (for example, information related to your health), they will share it with you immediately.

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

- You may benefit as a result of your participation in this study. There is, however, no guarantee that you will benefit from your participation in this study. 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 (if any). 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 $525 if you complete the entire study and all associated requirements.

You will receive your compensation after your last visit 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). Once activated, funds can take up to one week to be available. If you are unable to complete the entire study, the compensation provided will be based on the amount of the study you have completed as described below:

If you are enrolled into the study at visit 2, the compensation breakdown is as follows:

- Screening: $0
- Visit 2: $150
- Visit 3: $150
- Visit 4: $225

Once enrolled (completed visit 2 and received study product), 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 by 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 and dating 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.

VOLUNTARY PARTICIPATION

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.

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

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

- Missing scheduled study visits
- Not taking study products as directed
- Not completing required tests and documents
- Development of medical conditions or serious side-effects that may pose a health risk to you or the study outcomes as directed by the Sponsor

CONFIDENTIALITY OF RECORDS

- KGK Science contract research staff (the organization managing this study) will keep all your medical information confidential to the extent permitted by law.
- All research data (health information, past medical history, and test results from this study) will be kept in a locked file. Forms on which your information is entered will not contain your name (except for the study intake form and blood draw requisitions for off-site bloodwork, if requested).
- 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
    - The Sponsor (including its monitors and auditors)
    - Members of the Institutional Review Board - Advarra IRB (Institutional Review 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.
- Study records will be kept by the Sponsor for a minimum of 15 years after study completion, as required by Canadian clinical study regulations.
- Information from this study will be submitted to the Sponsor. Information sent from the study site will not contain your name.
- With your permission, your family doctor will be told about you taking part in this study.
- You have the right to check your study records and request changes if the information is incorrect.

THIS IS AN IMPORTANT DOCUMENT – KEEP FOR FUTURE REFERENCE

Participant Initials: _____

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

If you are completing this consent form electronically, you will be emailed a PDF copy once it is signed and dated. 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.

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 biospecimen 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 and destroy them.

Investigators, including investigators from collaborating institutions, can request this data and samples for new research. Samples and data may also be shared with outside non-profit academic investigators as well as with for-profit investigators 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.

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: Pro00067855.

THIS IS AN IMPORTANT DOCUMENT – KEEP FOR FUTURE REFERENCE

Participant Initials: _____

VOLUNTARY CONSENT TO PARTICIPATE

A randomized, triple-blind, placebo controlled, parallel clinical trial to investigate the safety and efficacy of Maizinol™ on sleep quality in a healthy population with difficulty falling asleep or staying asleep

Please answer **YES** or **NO** to the following questions:

1	Have you been given enough time to read and understand all pages in this Information and Consent form and the information it contains regarding the study 22UNRCZ01?	Yes / No
2	Have you been given enough time to consider whether to participate?	Yes / No
3	Is this document in a language you understand?	Yes / No
4	Have you been given the opportunity to ask all your questions you have regarding this study?	Yes / No
5	If you had questions, have all your questions been answered to your satisfaction?	Yes / No
6	Do you understand that you may consult the study doctor or the study staff, should anything become unclear or if you have any more questions?	Yes / No
7	Do you volunteer to be in this study of your own free will and without being pressured by the study doctor or the study staff?	Yes / No
8	Do you understand that you can leave the study at any time without giving a reason and without affecting your health care?	Yes / No
9	Do you understand the risks involved with participating in this study?	Yes / No
10	Do you agree to follow the study instructions provided to you by the study doctor and study staff?	Yes / No
11	Do you understand that you may not participate in another study while you are enrolled in this study?	Yes / No
12	Do you understand that your 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?	Yes / No
13	Do you understand that all your 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?	Yes / No

THIS IS AN IMPORTANT DOCUMENT – KEEP FOR FUTURE REFERENCE

Participant Initials: _____

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 know that the study products are for my use only. I will not share it with anyone and will store it in a safe place away from children, pets, or others for whom it is not intended. I will be given a signed and dated copy of this Information and Consent Form.

I voluntarily agree to be in this study.

_____
Printed Name of Participant

_____ _____ _____ AM/PM
Signature of Participant Date (mmm dd, yyyy) Time (00:00)

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

_____ _____
Signature of Person Explaining Consent Date (mmm dd, yyyy)

PRIMARY HEALTH CARE PROVIDER NOTIFICATION OPTION
I consent to having 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:

THIS IS AN IMPORTANT DOCUMENT – KEEP FOR FUTURE REFERENCE