# PARTICIPANT INFORMATION AND CONSENT FORM

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| **Sponsor/Study Title:** | **LifeWave Inc./ "A randomized, virtual, triple-blind, placebo-controlled, parallel clinical trial to investigate the efficacy and safety of the LifeWave Nirvana patch in healthy adults with moderate stress"** |
| **Protocol Number:** | **25LWCRL02** |
| **Principal Investigator:** ***(Study Doctor)*** | **David Crowley, MD** |
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## Making an Informed Decision

You are invited to participate in a virtual 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 electronically 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.

**To contact the study staff, please use the phone number or email address listed at the top of this page.**

## Background and Purpose

Stress is a normal human reaction in life when faced with daily challenges and can involve both physiological and psychological responses. Stress responses are normal and can be healthy, but prolonged periods of stress can lead to negative health consequences.

Various lifestyle strategies are suggested to help manage and reduce stress levels, including exercising, discontinuing tobacco and nicotine use, deep breathing, and mindfulness meditation. However, they require consistent commitment to be effective, which may be challenging to maintain over time. Therefore, safe and effective alternatives to pharmacotherapy (treatment with medicine) and lifestyle modifications are needed.

The objective of this study is to investigate the efficacy and safety of the LifeWave Nirvana patch in healthy adults with moderate stress. Efficacy means how well a treatment does what it is supposed to do. The LifeWave Nirvana patch uses a technology called photo biomodulation (PBM). The body's natural heat (infrared energy) activates the patch's materials to stimulate biological responses when placed on the skin at acupuncture points. This is non-invasive and does not put any chemicals or drugs into the body.

## Study Population

This study will include 50 healthy males and females 18 years of age and older who are experiencing moderate stress.

## How Long Is the Study?

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

## Study Design

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

**Randomized** — Upon completion of screening assessments, if you are eligible to participate, you will be randomly assigned by chance (like flipping a coin) to 1 of 2 study groups:

- LifeWave Nirvana patch group
- Placebo patch group

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

**Triple-blind** — Neither you, the study staff, nor the researchers analyzing the data will know which group you have been assigned to. However, if needed for your safety, the study staff can find out this information.

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

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

## Important Things to Note

- This study is conducted entirely virtually. All study-related activities, including providing your consent for participation, screening assessments, study visits and follow-ups, will take place remotely using secure digital platforms. There will be no in-person visits required for participation, but depending on your geographical location or personal preferences, you have the option to attend visits in person.

- To determine your eligibility to participate in this study, detailed information about your lifestyle, medications, and medical history will be collected. This information will help determine if you meet the necessary inclusion and exclusion criteria for this study.
- By signing this consent form, you are not guaranteed to be enrolled in the study. Your participation depends on meeting the study's specific eligibility criteria, which will be determined through a series of questions and assessments.
- This study uses competitive enrollment. Once 50 participants have enrolled and started the study, no additional participants will be accepted. This means that if you complete the screening phase, but the enrollment limit is reached before you are officially enrolled (which occurs when you are assigned to one of the study groups), you will not be able to continue in the study. Since you would not be officially enrolled, you would not be eligible to receive study compensation.
- You will receive study product at no cost to you.
- If you voluntarily agree to participate in this study, you must be willing to:
  - Maintain current lifestyle habits (diet, physical activity, medications, supplements, and sleep) as much as possible throughout the study.
  - Complete questionnaires and diaries associated with the study.
  - Apply the study device/patch on clean dry skin first thing each morning and remove after approximately 12 hours later or before bed for the duration of the study.
- You should not participate in the study if you have tattoos, skin conditions or sensitive skin on both the back of the neck and below the bellybutton. These are the places where you'll need to apply the patch. If only one of these areas has these conditions, you'll be asked to wear the patch on the area that is not affected.

## What Will Happen During This Study?

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

**Assessments and Procedures**

During this study, you will be required to complete the following:

Daily Assessments (Day 0-Day 28):

- **Electronic Daily Diary:** You will complete an online diary throughout the study. You will record the number of patches used throughout the day, time of day the patch(es) were applied and removed, total daily wear time, body site of application, lifestyle habits, change in medication/health and any adverse events (side-effects).

Day 0, Day (14±2) and Day (28±2) assessments:

- **Perceived Stress Scale (PSS):** This is a commonly used tool to measure how much stress you feel.
- **Profile of Moods States Questionnaire 2 (POMS-2):** This is a self-reported assessment tool that measures mood and helps identify mood disturbances.
- **PROMIS Sleep Disturbance Questionnaire:** This is a self-reported questionnaire that assesses sleep quality and disturbances.
- **RAND SF-36 Questionnaire:** This is a self-reported questionnaire that measures health-related quality of life.

**Schedule of Virtual Study Visits**

| **Screening/Baseline (Day 0; Visit 1)** |
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| • Informed consent for participation in the study will be obtained.<br>• After providing consent, you will receive an email with link to a screening assessment. You will be asked to enter details about your medical history, medications, demographics, and health status.<br>• You will complete questionnaires such as: PSS, POMS-2, PROMIS Sleep Disturbance Questionnaire and RAND SF-36 Questionnaire. Some of these questionnaires will be sent to you in a separate email.<br>• Once screening assessments are complete, study staff will review your information to determine if you are eligible to participate.<br>• If you are eligible, you will be randomized (randomly assigned to one of the study groups) and the study product will be shipped at no cost to you, along with instructions on how to use it.<br>• You will receive an email from KGK Science notifying you when the study product has been shipped. This e-mail will contain an orange button that you will need to click once you have received the study product.<br>• After receiving the study product, you will need to return to the email that notified you of its shipment, click the orange button, and complete the form to confirm receipt of the study product. |
| **Visit 2 (Day 14 ±2) and Visit 3 (Day 28 ±2)** |
| *A member of the study staff will connect with you via videocall for virtual assessments which include:*<br>• Review of your study diaries, including information about changes in your health, medications, and study product use.<br>• You will need to count the unused study product to help staff check if you have been using it as instructed.<br>• You will complete questionnaires such as: PSS, POMS-2, PROMIS Sleep Disturbance Questionnaire and RAND SF-36 Questionnaire. Some of these questionnaires will be sent to you in a separate email.<br>• You will receive your new study diaries (only at Visit 2). |

## Medications, Supplements, and Food/Drinks

**Prescribed Medications**

- You must continue taking any prescribed medications as directed by your healthcare provider throughout the study, unless they advise otherwise. Do not stop any regular medications in order to join the study unless explicitly instructed by your healthcare provider. Stopping regular medications without medical advice to join this study may pose serious health risks. If your healthcare provider recommends any new medication, changes to your current medication dose, or stopping a medication, notify the study staff immediately.

**Over-the-Counter (OTC) Medications, Supplements, and Foods/Drinks**

- Please disclose any over-the-counter (OTC) medications, supplements, and food or drinks you take in your screening forms to help us thoroughly evaluate your eligibility for the study. Additionally, report

any changes to these products and any OTC medications you take during the study (even if they are used on an "as needed" basis) in your study diaries.

## 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 for the past 1 year, have had a menstrual period in the past 1 year, or have not had any of the following surgeries: hysterectomy, bilateral oophorectomy, complete endometrial ablation, or bilateral tubal ligation) must agree to use a medically approved method of birth control for the duration of the study.

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 (must have been using it for at least 3 months)
- 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 are of child-bearing potential, you must self-report confirmation that you are not pregnant, do not plan to become pregnant, and agree to use a medically approved method of birth control for the duration of the study.

If you become pregnant during the study, you must stop wearing the study product immediately and contact the study staff. You will be withdrawn from the study and the study doctor will follow up with you until the child's birth, collect information about your pregnancy, its outcome, and the health of your child.

**Since the study product is investigational, there may be other risks that are unknown. Additionally, there may be unknown risks to a pregnancy, embryo, or fetus if you become pregnant.**

## Study Product Information

**LifeWave Nirvana patch**

LifeWave Nirvana patch is a wearable non-transdermal patch, which means that it does not deliver any active ingredients into the body through the skin. The patch is made of water, stabilized oxygen, stereoisomers (different forms of the same molecule) of organic sugars and stereoisomers of amino acids.

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

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

**Directions:**

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

## 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 using the study product. Potential side-effects of using the study product may include:

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

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

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

## Could I Have an Allergic Reaction?

It is possible for people to have allergic reactions to the study product. If you have a serious allergic reaction, it could be fatal. Read the study ingredients carefully to make sure you are not allergic to any of them. Some effects of an allergic reaction that could be a sign of a life-threatening (anaphylaxis) include:

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

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

Contact the study staff if you have questions about the signs or symptoms of any side-effects you read about in this consent form. Inform the study staff right away if you experience any side-effects, problems with your health or the way you feel during the study, and 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 completing 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 virtual study visits
- Not using the study product as directed
- Not completing required assessments or procedures
- Development of medical conditions or serious side-effects that may pose a health risk to you or the study outcomes

- The need for restricted medication(s) during the study
- If you become pregnant during the study

## New Findings

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

## Benefits

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

## Costs To You

- There is no cost to you to participate in the study. The study product will be provided and mailed to you at no cost.
- 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 $200 if you complete the entire study and all associated requirements.

You will receive your compensation after completion of the study on a ClinCard, which can be used like a prepaid Mastercard. It can be used anywhere that accepts Mastercard, or the funds can be withdrawn from an ATM (ATM fees apply). Processing times may apply before funds become available on your ClinCard. The Clincard and instructions on how to activate the card will be shipped to you along with the study product.

If you are enrolled into the study at Screening/Baseline (Day 0), the compensation breakdown is as follows:

- Virtual Screening/Baseline: $0
- Visit 2 (Day 14 ± 2): $75
- Visit 3 – End of Study (Day 28 ± 2): $125

Once enrolled, for any case in which you or the study doctor determine you cannot complete all of 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 complete the assessments that were scheduled for your End of Study visit (if you consent to doing so). If you complete the early termination visit and its assessments, you will be compensated $25.

## Compensation And Treatment for Injury

- In case of an injury or illness suffered while, and solely as a result of participating in this study, you will receive appropriate medical care. The Sponsor will cover necessary medical costs not covered by the provincial health plan or your private medical insurance (if any). By signing this form, you are not giving up your legal rights, nor releasing the study doctor or Sponsors from their legal and professional obligations.
- Be aware that the provincial health plan or your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

## Confidentiality of Records

- Staff at KGK Science (the contract research organization managing this study) will keep all your medical information confidential to the extent permitted by law.
- All research data (health information, past medical history, and test results from this study) will be kept in a secured location. Forms on which your information is entered will not contain your name (except for the signed consent form, the study intake form and/or external requisitions if applicable).
- Any of your personal information that is stored electronically will be password protected, accessible only to authorized personnel and coded wherever possible. Electronic data may be stored on secure servers which are physically located in Canada and/or the United States.
- You will not be identified in any publication that might result from the study. Unless required by law, only the following may have access to confidential study data (not your personal information) at the study site:
    - The study doctor and study staff
    - The Sponsor (including its monitors and auditors)
    - Members of the Research Ethics Board - Univo REB (an independent ethics committee that reviewed the ethical aspects of this study to help ensure that the rights and welfare of participants are protected and that the study is carried out in an ethical manner)
    - Government regulatory authorities including Health Canada and other foreign regulatory agencies.
- While the Sponsor will not have access to your personal identifying information, the study doctor, study staff, monitors, auditors, REB, and regulatory authorities may review study records, which could include your personal identifying information (such as the signed consent form) for compliance and verification purposes.
- All study data will be archived for a minimum of 15 years from the date of completion of the study in accordance with Health Canada regulatory requirements.
- Information from this study will be submitted to the Sponsor. Information sent from the study site will not contain your name.
- You have the right to check your study records and request changes if the information is incorrect.
- While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.

- As part of this research, you may be required to use one or more of the following: a phone or web 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.**

## 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 assessments and/or procedures;

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

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

## Voluntary Consent to Participate

By signing and dating this document I agree that I have been provided 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, Research Ethics Review Board, Health Canada and other foreign regulatory agencies. I understand that all my personal information will be treated as strictly confidential, except where disclosure is required by law, and will not be made publicly available; however, absolute confidentiality cannot be guaranteed.

I know that the study product is for my use only. I will not share it with anyone, and I will store it in a safe place away from children, pets, or others for whom it is not intended.

By signing and dating this document, I do not waive any of my rights under the law or release the study doctor or Sponsor from their legal and professional obligations. I understand that I am expected to keep a copy of this signed and dated consent form for my record.

**FOR ELECTRONIC CONSENT:**

For electronic consent, your name, digital signature, date and time of consenting will be added below by the consenting software. By adding your electronic signature, you consent to the material provided as if you were physically signing a hard copy of this document. By signing this informed consent document, you acknowledge that you have read and fully understand all the pages of the information presented in it.

**Participant -** I voluntarily agree to
participate in this study
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