RESEARCH PARTICIPANT INFORMED CONSENT FORM
SUBJECT INFORMATION

Sponsor: Freedom Laser Therapy

Protocol Number & Study Title: #20679 The Effects of an LED Face Mask & Neck and Chest Mask On Skin Health (NCT07025837)

Name of Person In Charge of the Research Study (Study Doctor/Investigator): Dr. Swathi Varanasi (Citruslabs)

Date: 14th October 2024

Telephone Number(s), Daytime/ After hours: +1 805-876-4484

CONCISE SUMMARY:

This study investigates the efficacy of the iRESTORE Illumina LED Face Mask and the iRESTORE Illumina LED Neck & Chest Mask in reducing the appearance of wrinkles, fine lines, dark spots, dull skin, crepey skin on the neck and chest, and other aging concerns. Over a period of 12 weeks, 38 female participants aged 25-55 will use the product for 10 minutes daily and undergo periodic questionnaires and photos to track changes.

If you are interested in learning more about this study, please continue to read below.

INTRODUCTION

You are invited to participate in a clinical research study conducted by Freedom Laser Therapy. This document outlines the study's purpose, procedures, potential risks, and benefits. Your understanding of these elements is crucial before deciding to participate.

The study aims to assess the effectiveness of the iRESTORE Illumina LED Face Mask and the iRESTORE Illumina LED Neck & Chest Mask in reducing the appearance of wrinkles, fine lines, pigmentation, redness, dull skin, crepey skin on the neck and chest, and other aging concerns. The study's outcome could offer valuable insights into the product's benefits and effectiveness.

Participants will use the iRESTORE Illumina LED Face Mask and the iRESTORE Illumina LED Neck & Chest Mask according to specific instructions over 12 weeks. During this period, your skin's response to the product will be monitored through photos and questionnaires.

Your participation is voluntary, and you have the right to withdraw at any time. The data collected will be confidential and used solely for research purposes. This ICF provides detailed information to help you make an informed decision about your participation.

ABOUT THE STUDY

The iRESTORE Illumina LED Face Mask and the iRESTORE Illumina LED Neck & Chest Mask are designed to rejuvenate the skin, targeting signs of aging. The study will explore the product's impact on

skin appearance and health over a 12-week period. Participants will use the iRESTORE Illumina LED Face Mask and the iRESTORE Illumina LED Neck & Chest Mask for 10 minutes daily.

It is hypothesized that regular use will lead to visible reductions in wrinkles, fine lines, and other aging signs.

This study is unique in its approach to evaluating a cosmetic product's effectiveness in a controlled, clinical setting. The data collected will contribute to understanding the product's impact on various skin types and conditions.

WHAT WILL WE ASK YOU TO DO?

Before the study begins, we will ask you to complete a Baseline questionnaire and take a Baseline photo of the face.

Upon completion of the Baseline requirements, you will be instructed to use the iRESTORE Illumina LED Face Mask and the iRESTORE Illumina LED Neck & Chest Mask as instructed for 10 minutes daily. For the face mask, mode 1 should be used for all sessions. The neck and chest mask does not have multiple settings.

During this study, you will complete questionnaires at home at Baseline, Week 2, Week 4, Week 6, Week 8, Week 10, and Week 12. Photos will be taken at Baseline and Week 12.

Your honest feedback and adherence to the usage instructions are crucial for the accuracy and reliability of the study results. All information will be collected securely and confidentially.

The information will be collected via a separate secure online portal to which you will be onboarded through the study staff, either via video chat or a phone call.

Study participants will only use products outlined in this consent form. If a study participant receives a product not listed in this consent form, they will set it aside and notify Citruslabs immediately.

HOW LONG IS THE STUDY?

You will participate in the study for 12 weeks.

WHAT HAPPENS WHEN I DECIDE THAT I WANT TO PARTICIPATE?

Upon deciding to participate, you will sign this ICF and undergo eligibility screening. If eligible, you will be enrolled and receive the product, along with instructions on its use and the study procedures. Your participation begins with the baseline survey and photo. You will continue to use the product and participate in surveys throughout the study.

ARE THERE ANY POTENTIAL RISKS?

Potential risks include contraindications with those who are taking medications that make them photosensitive.

WHAT ARE THE POTENTIAL BENEFITS?

Participants may experience plumped skin, smoothed fine lines and wrinkles, reduced pigmentation, improved skin tone and texture, calmed skin, reduced redness, firmer skin and elasticity, improved skin radiance, and reduction of crepey skin on the neck and chest.

COMPENSATION AND COST

If you complete the study, which includes all of the questionnaires and photos, you will receive a Visa gift card of $125 sent to the email address associated with this consent form at the end of your participation in the study. For security reasons, the compensation cannot be sent to an alternate address. You will not receive any other compensation.

Compensation in this study is contingent upon the completion of all study actions. This means that to receive compensation, you must complete all surveys, and photos as outlined here. If you do not complete all study actions for any reason, you are not eligible for compensation.

There will be no charge to you for your participation in this study. The test product will be sent to each participant without any cost.

Participant's Responsibilities:

- The Participant agrees to fully comply with all study-related activities and requirements outlined here which is in compliance with the study design.
- The Participant agrees to attend all scheduled study visits, at-home testing, and/or surveys and complete any required actions within the specified timeframes.

Compensation:

- In consideration for the Participant's time and commitment to the Study, the Participant will be eligible to receive compensation as outlined here.
- The Participant acknowledges and agrees that timely completion of all study actions is a prerequisite for eligibility to receive compensation.
- The Participant acknowledges that partial compensation is not provided.

Timely Completion Requirement:

- The Participant understands and agrees that failure to complete study actions within the specified timeframes may result in the Participant becoming ineligible for compensation.
- The Participant acknowledges that the Sponsor may, at its sole discretion, determine whether a delay in completing study actions is acceptable and whether compensation will be provided.

HOW WILL MY INFORMATION BE PROTECTED?

The Health Insurance Portability and Accountability Act (HIPAA) describes how your Protected Health Information (PHI) may be used, disclosed, and made accessible. You will be asked to login to a secured software (patient portal), accessed via the internet, using a login code and a password. The patient portal used for the data collection is HIPAA compliant, meaning your private information is protected by law. In order to confirm your identity, communicate with you, determine your eligibility, and send you the product, we will collect your name, address, phone number, email address, and date of birth. Through the surveys, we will be collecting personal health information related to the study.

The information we collect will be kept confidential and will be used only for the purpose of this study. Only the study staff involved in this study and the people overseeing the study including Argus IRB will have access to your study records and PHI. All reports and communications released from this study will identify participants by an identification number only and will not contain identifying information. The overall results of the study may be published; however, the identity of participants will not be included. Your right to access your PHI in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

WHOM DO I CONTACT IF I HAVE QUESTIONS OR PROBLEMS?

During your participation in this study with Citruslabs, should you experience an unintended health-related issue, you will immediately report your symptoms to Citruslabs. All reported information will be kept confidential to the extent allowed by applicable laws and regulations. The research team will report adverse events to the study Sponsor, regulatory authorities, and the Institutional Review Board (IRB) in accordance with the study protocol and regulatory requirements.

During the study, if you have any questions, concerns, or complaints about the study, please contact Dr Swathi Varanasi and team at +1 805-876-4484.

An Institutional Review Board (IRB) is an independent committee (group of people) established to help protect the rights and well-being of research subjects participating in research studies. The IRB reviews those studies. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, or if you do not want to talk to the investigator or study staff contact Argus IRB at argusirb@cox.net or call 520-298-7494.

Argus IRB has approved the information in this consent form and has given approval for the investigator to do the study. This does not mean Argus IRB has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

You will not lose any of your legal rights by agreeing to participate in this study.

You also understand that Freedom Laser Therapy, Citruslabs, and Argus IRB will keep your data confidential and that your name and other identifying information (such as email address) will never be used in any presentations, reports, or public documents related to this research study. You understand that your data and information will be analyzed as part of a group and that all study results will be presented in aggregate format.

My return of this form implies my consent to participate in this research, and I have been given a second copy of this form to keep for my records.

By signing this form, I confirm the following:

- I have read all of this consent form.
- All of my questions have been answered to my satisfaction.
- I can leave the study at any time without giving a reason and without penalty.
- I agree to the collection, use, sharing, and analysis of my personal health information and study information collected as part of this study by the sponsor and other authorized persons and regulatory agencies as described in this form.
- I will be given a copy of this signed and dated consent form to keep.
- I do not give up any legal rights that I would otherwise have if I were not in this study.

Exclusive Participation Agreement

As a participant in the Citruslabs study, I hereby confirm and agree to the following terms and conditions regarding my participation:

- Exclusive Participation: I affirm that I am not currently enrolled in any other clinical, medical, or therapeutic study, trial, or similar research activity. I further agree to refrain from enrolling in any other study during my participation in the Citruslabs study. I understand that my participation in this study requires my undivided and exclusive commitment to ensure the integrity and validity of the research results.
- Disclosure Requirement: I commit to immediately notifying the study coordinators at Citruslabs if there is any change in my participation status in other research studies during my tenure with this study. This includes any plans or intentions to join other studies.
- Consequences of Breach: I acknowledge and accept that if it is discovered that I am concurrently participating in another research study during my tenure with the Citruslabs study, I will be immediately removed from all Citruslabs studies.

- Forfeiture of Compensation: In the event of my removal due to breach of these terms, I understand that I will forfeit any compensation I might otherwise have been eligible to receive.

Your signature will be electronically captured if you agree to participate.

Participant Name	Signature	Date
Jodi Nicolli	jodi Nicolli	10/14/24

Person Obtaining Consent	Signature	Date

Keep a copy of this consent form for your records.

Image Publication Release & Photographic Consent Form

As part of the consumer perception study, you will need to take photographic images of your face at certain times during the study. This form is called an “Image Publication Release & Photographic Consent Form”, and once signed, it means that you grant Freedom Laser Therapy permission to use your photographic images that were produced for this study for their publications (for example, as “before and after pictures”). You will make no monetary or other claims against Freedom Laser Therapy for the use of the photograph(s) that were taken of your face for this study. Your name will not be used in any of the publications. You’ll receive photo guidelines about how you’re supposed to take the images. Your smartphone camera or any other digital camera will be sufficient for this, and you will not need to purchase any equipment.

If you have any questions or concerns about this form, please contact Dr Swathi Varanasi at +1 805-876-4484.

PARTICIPANT CONSENT

By signing below, you acknowledge that:

1) You are 18 years of age or older.
2) Hereby grant Freedom Laser Therapy permission to use the photographic images that were taken of you in this study for publication.
3) Hereby release Freedom Laser Therapy from any liability for any adverse events that might occur during the study.
4) Any questions you have about the use of your image have been answered satisfactorily.
5) There will be no further compensation for any photographs.
6) Your name will not be used in any publication.

I understand and agree to the conditions outlined in this Image Publication Release & Photographic Consent Form. I hereby allow Freedom Laser Therapy to use these photographs/images, and I give up any and all of my own future claims and rights to use these photographs/images.

Print Name: _____ Date: _____

Signature: _____

Bill of Rights for Human Subjects in Medical Research

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given an opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.