# The Effects of an LED Face Mask & Neck and Chest Mask On Skin Health

**Protocol Number: 20679**

**National Clinical Trial (NCT) Identified Number: NCT07025837**

**Principal Investigator: Swathi Varanasi, PharmD**

**Sponsor: Freedom Laser Therapy**

**Contract Research Organization: Citruslabs**

**Funded By: Freedom Laser Therapy**

**Version Number: v.1.0**

**06th September 2024**

**Summary of Changes from Previous Version:**

| Affected Section(s) | Summary of Revisions Made | Rationale |
|---|---|---|
| | | |
| | | |

## STATEMENT OF COMPLIANCE

The trial will be carried out in accordance with International Conference on Harmonisation Good Clinical Practice (ICH GCP), and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812)

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the Institutional Review Board (IRB) for review and approval. The protocol and consent form must be approved before enrolling any participant. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. In addition, all changes to the consent form will be IRB-approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

# 1 PROTOCOL SUMMARY

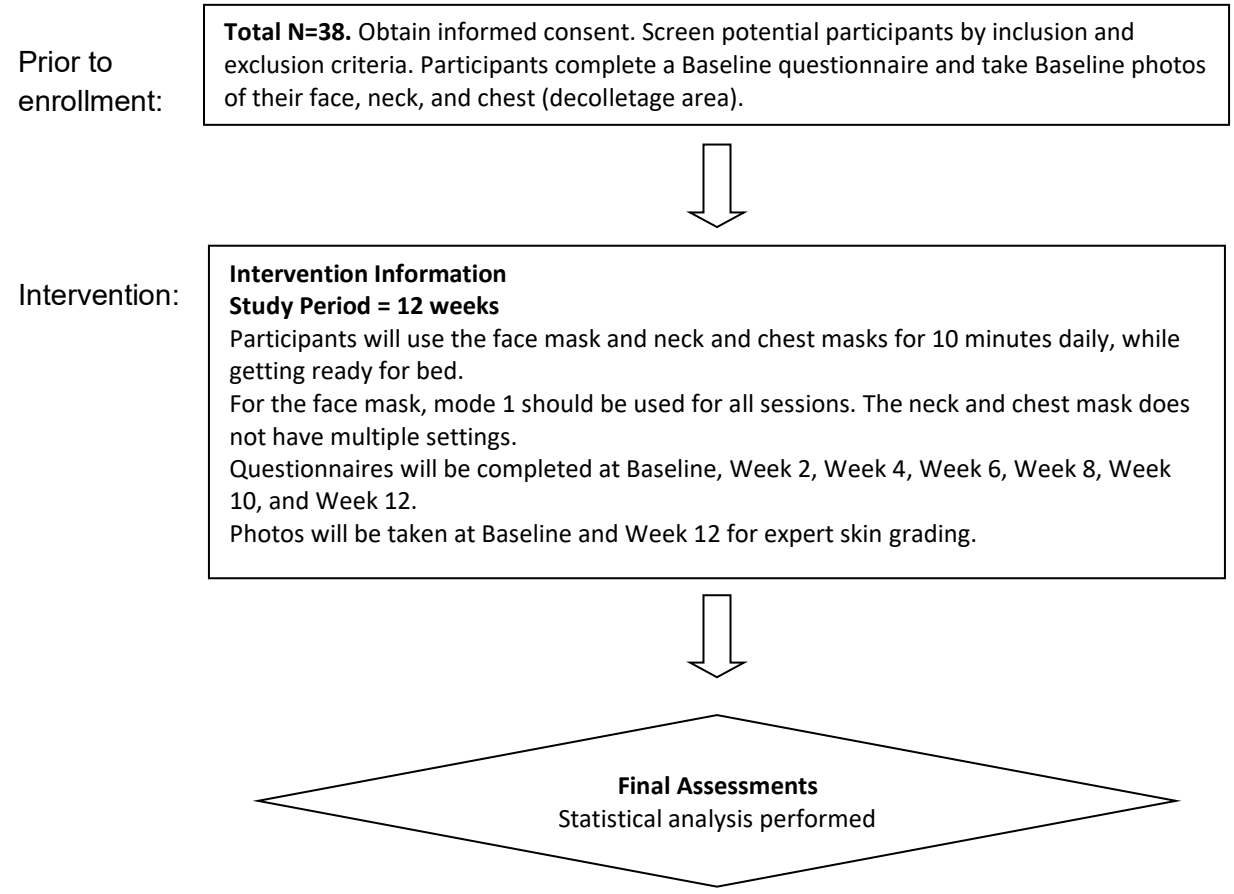
## 1.1 SYNOPSIS

| | |
|---|---|
| **Title:** | The Effects of an LED Face Mask & Neck and Chest Mask On Skin Health |
| **Study Type:** | Single Group, Virtual |
| **Product(s) being tested** | The iRESTORE Illumina LED Face Mask and The iRESTORE Illumina LED Neck & Chest Mask |
| **Study Intervention Description:** | This single-group study will involve 38 participants for a total of 12 weeks.<br><br>Participants will use the test products once daily for 10 minutes in the evening while getting ready for bed.<br><br>Participants will use Mode 1 only for all sessions of the face mask - the neck and chest mask does not have multiple settings.<br><br>Participants will complete questionnaires at Baseline, Week 2, Week 4, Week 6, Week 8, Week 10, and Week 12.<br><br>Participants will also provide photos of their faces at Baseline and Week 12 for dermatologist skin grading.<br><br>Participants will utilize the test products at home and complete questionnaires online. |
| **Objectives:** | *Primary Objective:* To examine the effectiveness of the iRESTORE Illumina LED Face Mask and The iRESTORE Illumina LED Neck & Chest Mask in improving skin health outcomes.<br><br>*Secondary Objective:* To assess changes in participant perception of skin health. |
| **Endpoints:** | *Primary Endpoint*: Improvements in skin health parameters will be evaluated by dermatologist grading at Baseline and Week 12.<br><br>*Secondary Endpoint:* Participant perceptions of skin health, including plumpness, fine lines and wrinkles, appearance of pigmentation, skin tone and texture, skin redness, firmness, and radiance, and the appearance of crepey skin will be evaluated through subject-specific questionnaires at Baseline, Week 2, Week 4, Week 6, Week 8, Week 10, and Week 12. |
| **Study population** | 38 female participants aged 25-55 |
| **Study Duration:** | 12 weeks |
| **Description of Sites/Facilities Enrolling Participants:** | Virtual |

| | |
|---|---|
| **Survey Milestones** | Baseline, Week 2, Week 4, Week 6, Week 8, Week 10, and Week 12. |
| **Photo Milestones** | Baseline and Week 12 |
| **Directions For Use:** | Participants will use the iRESTORE Illumina LED Face Mask and The iRESTORE Illumina LED Neck & Chest Mask for 10 minutes once daily while getting ready for bed.<br><br>Participants will use Mode 1 only for all sessions of the face mask. The neck and chest masks do not have multiple settings. Full instructions will also be written in the manual included with the kit.<br><br>**iRESTORE Illumina LED Face Mask**<br>Set Up<br>Connect the power cord to the mask. Attach the two parts of the upper strap to the mask<br>(labeled UL for Upper Left and UR for Upper Right). If desired, attach the lower straps as<br>well (labeled LL for Lower Left and LR for Lower Right). The lower straps are optional and<br>are designed to allow the user to pull the mask closer to the face.<br><br>Preparation<br>Cleanse your face to remove all makeup, skincare, dirt,<br>and oils. Place the mask comfortably on your face<br>and lightly tighten the straps. Ensure the mask is snug but not too tight.<br>Adjust the upper straps upward to relieve pressure.<br><br>Step 1<br>Press and hold (Power) button to turn on the mask. The mask enters P1 mode automatically.<br><br>Step 2<br>Once a mode is selected, press (Start/Pause) button to begin a 10-minute session, and<br>the indicator light will turn on. Once the session is complete, the indicator light will turn<br>off, and the mask will turn off automatically in 30 seconds. Note: If the (Start/Pause)<br>button is not pressed within 30 seconds once a mode is selected, the mask will turn off<br>automatically.<br><br>Step 3<br>If you need to pause the session at any time, press the (Start/Pause) button, and the<br>indicator light will flash. Press the (Start/Pause) button to resume the session, and the<br>indicator light will turn on. If the (Start/Pause) button is not pressed within 30 seconds<br>during a paused session, the mask will turn off automatically.<br><br>Step 4 |

| | |
|---|---|
| | Hold the (Power) button for several seconds if you need to turn off the mask. The<br>indicator light will turn off immediately; then, the mask will turn off in 30 seconds.<br><br>**iRESTORE Illumina LED Neck & Chest Mask**<br>Neck & Chest Mask<br>Set Up<br>Connect the power cord to the mask. For a full neck and chest treatment, attach the<br>lower straps (labeled LL for Lower Left and LR for Lower Right) to the two ends of the<br>mask. If you want to focus on treating the chest only, remove the lower straps and attach<br>the upper straps (labeled UL for Upper Left and UR for Upper Right) to the holes at the top<br>of the mask, then let it hang from your neck.<br>Preparation<br>Position the mask on your chest and around your neck, and lightly tighten the strap. Ensure the mask is snug<br>but not too tight to cause discomfort.<br><br>Step 1<br>Press and hold the power button to turn on the mask.<br><br>Step 2<br>Press the (Start/Pause) button to begin a 10-minute session; the indicator light will turn<br>on. After the session, the mask will automatically turn off in 30 seconds.<br>Note: If you don't<br>press the (Start/Pause) button within 30 seconds, the mask will shut off automatically.<br>Step 3<br>If you want to pause the session at any time, press the (Start/Pause) button, and the<br>indicator light will flash. Press the (start/pause) button to resume the session, and the<br>indicator light will turn on. If the (Start/Pause) button is not pressed within 30 seconds<br>during a paused session, the mask will turn off automatically.<br><br>Step 4<br>Hold the (Power) button for several seconds if you need to turn off the mask. The<br>indicator light will turn off immediately; then, the mask will turn off in 30 seconds. |
| **Compensation** | $125 Visa gift card |
| **Devices** | Phone/Digital Camera (participants must provide)<br>iRESTORE Illumina LED Face Mask (sponsor provides)<br>iRESTORE Illumina LED Neck & Chest Mask (sponsor provides) |

## 1.2 SCHEMA


Prior to enrollment:
**Total N=38.** Obtain informed consent. Screen potential participants by inclusion and exclusion criteria. Participants complete a Baseline questionnaire and take Baseline photos of their face, neck, and chest (decolletage area).
Intervention:
**Intervention Information**
**Study Period = 12 weeks**
Participants will use the face mask and neck and chest masks for 10 minutes daily, while getting ready for bed.
For the face mask, mode 1 should be used for all sessions. The neck and chest mask does not have multiple settings.
Questionnaires will be completed at Baseline, Week 2, Week 4, Week 6, Week 8, Week 10, and Week 12.
Photos will be taken at Baseline and Week 12 for expert skin grading.
**Final Assessments**
Statistical analysis performed

### 1.3 SCHEDULE OF ACTIVITIES (SOA)

| Procedures | Screening | Intervention | Conclusion |
|---|---|---|---|
| **Informed Consent** | x | | |
| **Demographics** | x | | |
| **Inclusion/ Exclusion** | x | | |
| **Administer Study Intervention** | | x | |
| **Surveys** | x | x | x |
| **Photos** | x | | x |
| **Adverse Event Review and Evaluation** | x | x | x |

## 2 INTRODUCTION

### 2.1 STUDY RATIONALE

The effects of aging and poor skincare on the face, neck, and chest can be significant, leading to various visible changes in skin appearance and texture. As we age, our skin naturally produces less collagen and elastin, proteins that provide structural support and elasticity[1]. This reduction, combined with environmental factors like sun exposure and pollution, contributes to the development of wrinkles, fine lines, and sagging skin[2,3].

The decolletage area, which includes the neck and upper chest, is particularly vulnerable to aging signs due to its thin skin and frequent sun exposure[4]. Common symptoms in this region include vertical wrinkles, crepey skin, sun spots, and overall skin discoloration. The face often experiences similar issues, along with the formation of age spots, rough patches, and a loss of volume that can lead to a sunken appearance[5].

Poor skincare habits exacerbate these natural aging processes. Neglecting sun protection, failing to moisturize regularly, and not incorporating anti-aging ingredients into one's routine can accelerate skin damage[6].

Light therapy devices have emerged as a promising treatment for aging skin. These devices use specific wavelengths of light to stimulate collagen production, improve skin texture, and reduce the appearance of fine lines and wrinkles[7]. LED (Light Emitting Diode) therapy, in particular, has

shown benefits in skin rejuvenation[8]. Red light therapy can boost collagen production and improve skin elasticity, while blue light therapy may help with acne and inflammation[9,10].

With this in mind, Freedom Laser Therapy has designed a face mask and neck and chest mask that utilize 360 LEDs for the face mask and 230 LEDs for the neck & chest mask to provide firmer, smoother, and clearer skin.

### 2.2 RISK/BENEFIT ASSESSMENT

Immediate *risks*: People taking or using medications that make their skin photosensitive should not take part in this study.

Long-term *risks*: There are no expected long-term risks associated with this product.

Immediate *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 neck and chest.

Long-term *benefits*: Participants may experience improvements in overall mental health and well-being due to the immediate benefits of the product.

## 3 OBJECTIVES AND ENDPOINTS

| OBJECTIVES | ENDPOINTS | TIMEPOINTS | ASSESSED BY | JUSTIFICATION FOR ENDPOINTS |
|---|---|---|---|---|
| *Primary Objective:* To evaluate changes in overall skin appearance, as measured by dermatologist skin grading. | Improvement in Skin Appearance | Baseline and Week 12 | Photographs via Dermatologist Skin Grading | Standardized photographs provide objective data on the changes in skin appearance, specifically targeting wrinkles, fine lines, and other signs of aging. |

| | | | | |
|---|---|---|---|---|
| *Secondary Objectives:* To assess changes in a range of skin health parameters. | Improvement in skin plumpness, fine lines and wrinkles, pigmentation, tone and texture, redness, firmness, elasticity, radiance, and appearance of crepey skin. | Baseline, Week 2, Week 4, Week 6, Week 8, Week 12 | Questionnaires | Self-reported questionnaires provide subjective data on perceived changes in wrinkles and fine lines. |

# 4 STUDY DESIGN

## 4.1 OVERALL DESIGN

This 12-week single-group, virtual clinical study is designed to evaluate the efficacy of the iRESTORE Illumina LED Face Mask and The iRESTORE Illumina LED Neck & Chest Mask. The study will involve 38 participants, aged between 25 and 55 years, with self-reported skin issues, who will use the devices once daily for 10 minutes daily for 12 weeks.

Data collection will include questionnaires at Baseline, Week 2, Week 4, Week 6, Week 8, Week 10, and Week 12. In addition, participants will provide photos at Baseline and Week 12 to assess changes in skin health and appearance.

## 4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

A single-group study is an appropriate design to understand the efficacy and safety of the test product. A design that encompasses 12 weeks is also long enough to determine if the supplement is effective at improving skin health. The data collection intervals for this trial were chosen to minimize the burden on the patients (i.e., not having to travel to a clinic) while still collecting valuable data about the efficacy of the test product over time.

## 4.3 JUSTIFICATION FOR DOSE

The chosen duration and frequency of application are based on established dermatological guidelines for similar treatments. This regimen is believed to provide sufficient exposure to light therapy to elicit measurable changes in skin condition without overexposure or causing undue stress to the skin. The dose is designed to balance efficacy with safety, ensuring that participants experience the full benefits of the treatment without significant risk of adverse effects.

### 4.4 End of Study Definition

The study concludes after 12 weeks, with the final collection of data, photos, and participant feedback. Adherence to ethical principles and participant safety is paramount throughout the trial process. Should any significant adverse events arise, the study may be adjusted or halted to prioritize participant well-being.

## 5 STUDY POPULATION

### 5.1 Inclusion Criteria

To be eligible to participate in this study, an individual must meet all of the following criteria:

- Female
- Aged 25-55 years.
- Willing to follow the study protocols.
- Self-reported issues with at least two of the following:
    - Fine lines
    - Wrinkles
    - Hyperpigmentation
    - Dark spots
    - Reduced elasticity
- Self-report concerns with at least one of the following:
    - Crepey skin on the neck and chest
    - Sun damage on neck and chest
- Willing to avoid introducing any new products, prescription medications, or supplements that target skin health during the study period.
- If taking oral supplements or herbal remedies targeted at skin health and appearance, have been consistently taking these for at least 3 months prior to starting the study.
- Is willing to maintain the routine of any oral supplements or herbal remedies targeted at skin health and appearance for the duration of the study.
- Has been using the same skincare routine for at least one month prior to the study start date.
- Willing to maintain the same skincare routine and products throughout the study.
- Willing to avoid direct sun exposure during the study duration
- Willing to wear sunscreen if have to be in the sun

### 5.2 Exclusion Criteria

An individual who meets the following criteria will be excluded from participation in this study:

- Anyone who is extremely satisfied with their skin.
- Anyone who has any chronic health conditions such as oncological (cancer) or psychiatric disorders.
- Anyone who is planning to undergo facial treatments during the study period, including botox, dermal filler, chemical peels, etc. or has experienced any of these treatments in the last 3 months.

- Anyone diagnosed with a skin condition affecting the face and/or neck who has had an active flare-up or breakout within the last year. This includes but is not limited to acne, eczema, psoriasis, rosacea, seborrheic dermatitis, vitiligo, urticaria (hives), warts, atopic dermatitis, melasma, and contact dermatitis.
- Currently using any prescription medications that may affect the skin condition including but not limited to the following:
    - Corticosteroids like prednisone, methylprednisolone
    - Antipsychotics like olanzapine (Zyprexa), risperidone (Risperdal), quetiapine (Seroquel)
    - SSRIs and SNRIs like fluoxetine (Prozac), sertraline (Zoloft), venlafaxine (Effexor)
    - Anticonvulsants like phenytoin (Dilantin), lamotrigine (Lamictal), and carbamazepine (Tegretol)
    - Antihypertensives like lisinopril (Zestril), amlodipine (Norvasc), and propranolol (Inderal)
    - Antithyroid medications like Tapazole (methimazole), Propyl-Thyracil (propylthiouracil)
- Anyone with a history of skin cancer or precancerous skin lesions on the face.
- Anyone who has any known serious allergic reactions that require the use of an Epi-Pen.
- Anyone who has any known allergies to ingredients commonly found in skincare products.
- Anyone who is pregnant, breastfeeding, or trying to conceive
- Anyone who cannot/will not commit to the study protocol.
- Anyone with a history of substance abuse.
- Anyone who has undergone an invasive medical procedure in the three weeks prior to the study or has a procedure planned during the study duration.
- Anyone with a known allergic reaction to aluminum or plastics.
- Anyone who suffers from any photosensitive disorder (sensitization to light).
- Anyone with uncontrolled acne.
- Anyone taking any prescription medication, over-the-counter supplements, or herbal supplements regularly (three or more days per week) that can cause photosensitivity including but not limited to the following:
    - Antibiotics like tetracyclines (e.g., doxycycline, tetracycline) or sulfonamides (e.g., Bactrim), fluoroquinolones (e.g., ciprofloxacin, levofloxacin)
    - Antifungals like Griseofulvin or Vfend (voriconazole)
    - Diuretics like drugs ending in -thiazides
    - NSAIDs like ibuprofen and Aleve (naproxen)
    - Retinoids or Vitamin A (e.g., Accutane (isotretinoin), (Retin-A) tretinoin
    - Antidepressants (e.g., SSRIs, Elavil (amitriptyline), Tofranil (imipramine)
    - Antihistamines like Phenergan (promethazine)
    - Antimalarial medications
    - Statins like Lipitor (atorvastatin), Zocor (simvastatin)
    - Antiarrhythmics like Pacerone (amiodarone)
    - St. John’s wort
- Anyone who suffers from light-induced headaches or migraines.
- Anyone with a medical history of seizures or epilepsy triggered by light.
- Anyone with an electronic implanted device such as a defibrillator, neurostimulator, pacemaker, or ECG monitor.
- Anyone with a known history of carotid artery disease, stroke or transient ischemic attack (TIA), carotid stenosis, unstable blood pressure, easy fainting, thyroid disease, or of individuals about to undergo surgical procedures in the neck area.
- Anyone who has stopped hormonal birth control in the past month.

### 5.3 PARTICIPANT COMPENSATION

Participants will each receive a $125 Visa gift card. Participants will also be permitted to keep the iRESTORE Illumina LED Face Mask and iRESTORE Illumina LED Neck & Chest Mask.

### 5.4 JUSTIFICATION OF SAMPLE SIZE

A sample size of 38 participants provides a balance between obtaining statistically significant results and maintaining a manageable cohort for detailed analysis and follow-up.

## 6 STUDY INTERVENTION

### 6.1 STUDY INTERVENTION

- Participants will be sent one iRESTORE Illumina LED Face Mask and one iRESTORE Illumina LED Neck & Chest Mask.
- Participants will use both products for 10 minutes daily in the evening. For the face mask, Mode 1 should be used for all sessions. The neck and chest mask does not have multiple settings.
- Questionnaires will be completed at Baseline, Week 2, Week 4, Week 6, Week 8, Week 10, and Week 12.
- Photos will be taken at Baseline and Week 12.

### 6.2 INTERVENTION FORMULATION

N/A

### 6.3 RANDOMIZATION AND BLINDING

There will be no randomization or blinding in this trial.

### 6.4 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time upon request.
An investigator may discontinue or withdraw a participant from the study for the following reasons:

- Pregnancy.
- Significant study intervention non-compliance.
- If any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant.
- Disease progression which requires discontinuation of the study intervention.
- If the participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation.

- Participants should be withdrawn from study if they start on a new drug or receive antibiotics.

The reason for participant discontinuation or withdrawal from the study will be recorded on a Case Report Form (CRF). Participants who sign the informed consent form but do not receive the study intervention may be replaced. Participants who sign the informed consent form, and receive the study intervention, and subsequently withdraw, or are withdrawn or discontinued from the study, will not be replaced.

### 6.5 PHOTO INSTRUCTIONS

Photographs will be taken at Baseline and Week 12 to document changes in appearance.

**Face guidelines:**

- You will be required to provide photos taken straight on, directly facing the camera, and from the sides at each measurement time point.
- Hair should be tied back.
- The photo should include your full face/head only, with no more than the top of your shoulders visible.
- No cropping: your full face, head, and ears should be included.
- Please use natural light, in a direction that your phone does not cast a shadow on your face when taking the photo, without using the flash.
- Do not use any type of camera filter setting. No makeup should be worn. Neutral facial expression.
- If possible, take your photos in the same location, at the same time of day, and in the same lighting at each check-in.

**Neck and Chest Guidelines:**

- The photo should be taken straight ahead.
- Please use natural light, in a direction that your phone does not cast a shadow on your face when taking the photo, without using the flash.
- Do not use any type of filter setting. No makeup should be worn. Neutral facial expression.
- If possible, take your photos in the same location, at the same time of day, and in the same lighting at each check-in.

### 6.6 REQUIRED DEVICES

Smartphone or digital camera to be provided by participants. iRESTORE Illumina LED Face Mask and The iRESTORE Illumina LED Neck & Chest Mask will be provided by the sponsor.

## 7 STATISTICAL CONSIDERATIONS

Following data collection and the completion of the trial, the data will be analyzed by Citruslabs to determine the effect of the intervention. Repeated-measure, between time points, statistical tests will be used to examine changes in primary and secondary endpoints versus the Baseline.

# 8 CONSENT, PRIVACY AND OTHER POLICIES

## 8.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

Consent forms describing in detail the study intervention, study procedures, and risks are given to the participant and written documentation of informed consent is required prior to starting intervention/administering study intervention. The following consent materials are submitted with this protocol: informed consent form, photographic consent form, patient bill of rights.

## 8.2 CONSENT PROCEDURES AND DOCUMENTATION

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Consent forms will be Institutional Review Board (IRB)-approved and the participant will be asked to read and review the document. These documents will explain the research study to the participant and answer any questions that may arise. A verbal or written explanation will be provided in terms suited to the participant's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participants should have the opportunity to discuss the study with their family or surrogates or think about it prior to agreeing to participate. The participant will sign the informed consent document prior to any procedures being done specifically for the study. Participants must be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. A copy of the informed consent document will be given to the participants for their records. The informed consent process will be conducted and documented in the source document (including the date), and the form signed, before the participant undergoes any study-specific procedures. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

## 8.3 CONFIDENTIALITY AND PRIVACY

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their interventions. This confidentiality is extended to cover testing of biological samples and genetic tests in addition to the clinical information relating to participants (not applicable for this study). Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any third party without prior written approval of the sponsor.

The study participant's contact information and records will be securely stored on an AWS server. Participant's identities are verified using Stripe Identity, which identifies potential fraudulent users. Stripe Identity deletes user data after it is complete and limits access to sensitive data. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, or sponsor requirements.

## 8.4 Data Collection and Management Responsibilities

Data collection is the responsibility of Citruslabs who is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

Trial data will be entered into a 21 CFR Part 11-compliant data capture system provided by Citruslabs. The data system includes password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate. Clinical data will be entered directly from the source documents.

## 8.5 Protocol Deviations

A protocol deviation is any noncompliance with the clinical trial protocol, International Conference on Harmonisation Good Clinical Practice (ICH GCP), or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the CRO staff. As a result of deviations, corrective actions are to be developed by the trial administrator (Citruslabs) and implemented promptly.

It is the responsibility of Citruslabs to use continuous vigilance to identify and report deviations within 7 working days of identification of the protocol deviation, or within 7 working days of the scheduled protocol-required activity. Protocol deviations must be sent to the reviewing Institutional Review Board (IRB) per their policies. Citruslabs is responsible for knowing and adhering to the reviewing IRB requirements.

## 8.6 Publication and Data Sharing Policy

This study will be conducted in accordance with the following publication and data sharing policies: the study may be published in an open-access preprint server. The study administrators (Citruslabs) will be acknowledged in any publications relating to this study. This trial may be registered with clinicaltrials.gov and results may be submitted to clinicaltrials.gov following publication. No part of this study, including protocol and results, may be published in any form without explicit prior approval in writing by the study sponsor.

## 8.7 Conflict of Interest Policy

The independence of this study from any actual or perceived influence is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial.

The sponsor has a conflict of interest, in that they may benefit financially from the success of the study. To manage the conflict of interest, an independent third party (Citrusabs) will be handling all design and administration of participant-focused materials, all participant recruitment and data gathering, and data analysis.

## 9 REFERENCES


1. Dierckx S, Patrizi M, Merino M, González S, Mullor JL, Nergiz-Unal R. Collagen peptides affect collagen synthesis and the expression of collagen, elastin, and versican genes in cultured human dermal fibroblasts. *Frontiers in Medicine*. 2024;11. doi:10.3389/fmed.2024.1397517
2. Wong QYA, Chew FT. Defining skin aging and its risk factors: a systematic review and meta-analysis. *Sci Rep*. 2021;11:22075. doi:10.1038/s41598-021-01573-z
3. Robic J, Lata W, Nkengne A, Bigouret A, Vie K. The impact of air pollution on the facial skin of Caucasian women using real-life pollutant exposure measurements. *Skin Res Technol*. 2024;30(7):e13669. doi:10.1111/srt.13669
4. Age and the neck's "décolleté syndrome" - PubMed. Accessed September 6, 2024. https://pubmed.ncbi.nlm.nih.gov/4013374/
5. Kligman AM, Koblenzer C. Demographics and psychological implications for the aging population. *Dermatol Clin*. 1997;15(4):549-553. doi:10.1016/s0733-8635(05)70464-2
6. Geng R, Kang SG, Huang K, Tong T. Boosting the Photoaged Skin: The Potential Role of Dietary Components. *Nutrients*. 2021;13(5):1691. doi:10.3390/nu13051691
7. Ganceviciene R, Liakou AI, Theodoridis A, Makrantonaki E, Zouboulis CC. Skin anti-aging strategies. *Dermatoendocrinol*. 2012;4(3):308-319. doi:10.4161/derm.22804
8. Sanclemente G, Medina L, Villa JF, Barrera LM, Garcia HI. A prospective split-face double-blind randomized placebo-controlled trial to assess the efficacy of methyl aminolevulinate + red-light in patients with facial photodamage. *J Eur Acad Dermatol Venereol*. 2011;25(1):49-58. doi:10.1111/j.1468-3083.2010.03687.x
9. Couturaud V, Le Fur M, Pelletier M, Granotier F. Reverse skin aging signs by red light photobiomodulation. *Skin Res Technol*. 2023;29(7):e13391. doi:10.1111/srt.13391
10. Wheeland RG, Dhawan S. Evaluation of self-treatment of mild-to-moderate facial acne with a blue light treatment system. *J Drugs Dermatol*. 2011;10(6):596-602.