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# Informed Consent

**Study:** An 18 Week Study to Assess the Efficacy of a Test Product Used in Combination with a Currently Marketed Prescription Product
**Principal Investigator:** Anna Hardy
**After Hours Emergency Contact:** 201-331-9400

**INTRODUCTION**
You are being asked to take part in a clinical research study conducted by Validated Claim Support, LLC (VCS). Your participation is voluntary. This document outlines what the study involves, including procedures, risks, compensation and benefits, so you can make an informed decision on whether you'd like to participate or not. If you have any questions or need clarification, please ask a study staff member before signing. You will receive a signed copy of this consent form for your records.

**STUDY PURPOSE**
The purpose of this study is to assess the efficacy (ability to produce a desired or intended result) of a topical product (applied to the skin) to improve skin lightness, skin condition and appearance (hyperpigmentation [dark spots], brightness/radiance [healthy vibrant appearance], skin texture [smoothness]) on the face over a period of eighteen (18) weeks. The data collected may support the company contracting this study in developing marketing claims for their product.

**WHO CAN BE ON THIS STUDY?**
To join this study:

You must meet each of the following requirements:

1. Female subjects of any race, in good general health, aged 18-75 years old, inclusive at enrollment.
2. Individuals with facial hyperpigmentation (dark spots) and/or melasma (brown or gray-brown patches on the skin).
3. Individuals willing to use a generic 4% Hydroquinone (a skin-lightening agent used to treat hyperpigmentation) prescription topical cream up to 10 weeks.
4. Individuals willing to refrain from use of other drugs or skincare intended to treat hyperpigmentation, other than study specific products (prescription drug, test product, SPF 50)
5. Individuals who are able to cooperate with the Principal Investigator and study personnel throughout the duration of the study and are willing to comply with all study procedures, methods, evaluations, and study product use.
6. Individuals who are able to read, understand and willing to sign an informed consent for this specific study and have completed all site required documentation prior to study enrollment (Registration and Medical History).
7. Individuals who are able to receive emails on their cellular phones and are capable of completing electronic Informed Consents, Photo Model Releases, and/or Questionnaires on their device.
8. Individuals willing to be photographed and sign a model release.



AIRB Approved
Christopher Staab
DATE 8 /13 /2025

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If even one of the following applies to you, you cannot be in this study:

1. Individuals with known allergies and/or reactions to Hydroquinone.
2. Individuals currently participating in other clinical studies that are testing a face product.
3. Individuals with uncontrolled medical condition(s), including dermatological (skin) problems, which could put them at risk in the opinion of the Principal Investigator or compromise the study outcome and/or chronic or serious diseases and conditions which would prevent participation in this clinical study such as cancer, AIDS, insulin-dependent diabetes, renal (kidney) impairment, mental illness, and/or drug/alcohol addiction.
4. Individuals with a history of melanoma, or a treated skin cancer within the last 5 years.
5. Individuals who are pregnant, lactating (producing breastmilk and/or breast feeding), or planning to become pregnant. Individuals who become pregnant during the study must inform the Principal Investigator immediately.
6. Individuals who are unreliable or unlikely to be available for the duration of the study.
7. Individuals with a history of allergic reactions, skin sensitization and/or known allergies to cosmetic and personal care products/ingredients.
8. Individuals who are immunocompromised (weakened immune system).
9. Individuals who are employees of VCS, other testing firms/laboratories, consumer product, and/or raw goods manufacturers/suppliers.
10. Individuals who are unable to communicate or cooperate with the Principal Investigator/study personnel due to language problems, poor mental development, or impaired cerebral (brain) function.
11. Individuals who started hormones within the last three months preceding the commencement (before the beginning) of the study.
12. Individuals who are using oral contraception (birth control pills) for less than three months before study commencement or who have changed their contraceptive method within the three months before the Baseline visit or planning to modify their contraception treatment within the duration of the study.
13. Individuals who have regular salon and/or dermatological procedures that can interfere with study results (Microdermabrasion, Fillers, Facial Peels, etc.) and are not willing to stop throughout the study.
14. Individuals with facial tattoos and facial piercings (that can't be removed).
15. Individuals with tattooed/permanent make up (i.e., eyeliner, eyebrows, lip liner, etc.), eyebrow microblading, and/or eyelash extensions.
16. Individuals who plan to change their hairstyle throughout the course of the study or who wear hair coverings regularly (i.e., wigs, coloring, extensions, etc.).

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**PROHIBITIONS & RESTRICTIONS**

For the duration of the study, you must not:

- Use other drugs or skincare intended to treat hyperpigmentation, other than study specific products (prescription drug, test product, SPF 50)
- Be exposed to excessive/direct sun exposure for the purpose of tanning during the study. Provided SPF must be used and reapplied as needed to avoid interactions with the prescription product.
- Use self-tanning products or tanning beds during the study.
- Initiate (start) the use of any new cosmetic/personal care products on the test area during the study.
- Use other toner products.

**STUDY PROCEDURES**

You will be one of approximately forty (40) participants. You must:

- Attend all scheduled visits.
- Complete the check in questionnaires at Weeks 5 and 14 at home (to confirm correct use of product and if you have any questions about the study or test products).
- Use the study product(s) exactly as instructed and complete a Daily Log (if applicable)
- Follow all directions given to you by study staff.

The test products will be: Niacinamide Brightening Toner (Test) and Placebo (having no effect) Facial Toner (Control). You will be given one of the two test products according to a randomization (assigned by chance, like the toss of a coin).

You will use the test product as follows:

**Facial Toner (Test) (this product is marketed):** Dispense onto a cotton round (provided) and gently sweep (wipe) over the cleansed face once in the morning. For external use. Avoid contact with eyes.

**Facial Toner (Control) (this product is investigational):** Dispense onto a cotton round (provided) and gently sweep (wipe) over the cleansed face once in the morning. For external use. Avoid contact with eyes.

The following support products must also be used: 4% Hydroquinone (prescription) and SPF- Banana Boat Light As Air Sunscreen Lotion UVA/UVB Broad Spectrum SPF 50+.

You will use the support product as follows:

**SPF:** Apply liberally to the face during the daytime at least once. Reapply as needed, after sweating or swimming, or whenever expecting prolonged (more than 90 minutes) sun exposure. Avoid contact with eyes.

**4% Hydroquinone:** Apply to the affected areas on the face and rub in well twice daily, in the morning and before bedtime, or as directed by the physician. Apply during the first 2 months of this study.

Morning- Apply as follows:

1. Wash and dry face
2. Apply toner and allow to dry
3. Apply 4% hydroquinone and allow to absorb (for the first 10 weeks; will be collected at the Week 10 visit)

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4. Apply SPF and allow to absorb
5. Apply makeup (if using)

Before bedtime- Apply as follows:

1. Wash and dry face
2. Apply 4% hydroquinone and allow to absorb (for the first 10 weeks; will be collected at the Week 10 visit).

Below is a detailed breakdown of what you can expect for each visit:

Visit 1- Screening/Washout Visit (Duration approximately 60 minutes)
You will report to the test center with a clean face, having removed all makeup and washed the night before and having not applied any products after washing. Do not apply any products on the morning of your visit, including cleanser. You will sign a copy of this consent form and a photo model release and be screened for eligibility. If qualified, you will undergo a brief medical assessment by a board-certified Dermatologist. If you continue to qualify, you will receive screening instructions and the SPF product. Upon completion of all procedures, you will be reminded of your next visit and dismissed from the test center.

Visit 2- Baseline Visit (Duration approximately 60 minutes)
You will report to the test center with a clean face, having removed all makeup and washed the night before and having not applied any products after washing. Do not apply any products on the morning of your visit, including cleanser. You will be asked about any changes to your health and medication. You will wash your face on site (Using Cetaphil Daily Facial Cleanser- Apply a small amount onto wet skin and rub gently. Rinse. Pat dry.) and sit quietly for at least fifteen (15) minutes to allow your skin to acclimatize (get used to) to the test center environment (temperature-controlled 20°C to 24°C [68°F to 75°F]). After acclimation you will undergo, expert grading, instrumental assessments and VISIA-CR imaging. You will be given the test product and the prescription product, written and verbal use instructions and a log to track product use. Upon completion of all procedures, you will be reminded of your next visit and dismissed from the test center.

No Visit- Week 5 Check-In (Duration approximately 5 minutes)
You will be asked to answer questions to confirm compliance with test product use. Using your mobile telephone, you will receive a text message with a link to access and complete the questionnaire online via Datacapt. This will need to be completed by 1:00PM.

Visit 3- Week 10 Visit (Duration approximately 60 minutes)
You will report to the test center with a clean face, having removed all makeup, washed your face and used the prescription product as directed the night before. Do not apply any other products after using the prescription product. Do not apply any products on the morning of your visit, including cleanser. You will be asked about any changes to your health and medication. You will wash your face on site (Using Cetaphil Daily Facial Cleanser- Apply a small amount onto wet skin and rub gently. Rinse. Pat dry.) and sit quietly for at least fifteen (15) minutes to allow your skin to acclimatize (get used to) to the test center environment (temperature-controlled 20°C to 24°C [68°F to 75°F]). Your test product and log will be

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collected and reviewed for compliance with product use instruction and then returned to you. The prescription product will be collected and not be returned to you. After acclimation you will undergo expert grading, instrumental assessments and VISIA-CR imaging.
Upon completion of all procedures, you will be reminded of your next visit and dismissed from the test center.

No Visit- Week 14 Check-In (Duration approximately 5 minutes)

You will be asked to answer questions to confirm compliance with test product use. Using your mobile telephone, you will receive a text message with a link to access and complete the questionnaire online via Datacapt. This will need to be completed by 1:00PM.

Visit 4- Week 18 Visit (Duration approximately 60 minutes)
You will report to the test center with a clean face, having removed all makeup and washed the night before and having not applied any products after washing. Do not apply any products on the morning of your visit, including cleanser. You will be asked about any changes to your health and medication. You will wash your face on site (Using Cetaphil Daily Facial Cleanser- Apply a small amount onto wet skin and rub gently. Rinse. Pat dry.) and sit quietly for at least fifteen (15) minutes to allow your skin to acclimatize (get used to) to the test center environment (temperature-controlled 20°C to 24°C [68°F to 75°F]). You will complete a subjective questionnaire. Your test product and log will be collected and reviewed for compliance with product use instructions. After acclimation you will undergo expert grading, instrumental assessments and VISIA-CR imaging. Upon completion of all procedures, you will be dismissed from the test center and your payment card will be loaded in two (2) business days.

**EVALUATION METHODS**
Instrumental Evaluations
The Chromameter measures the color of your skin using a small probe which will be placed in contact with your skin for approximately 10 seconds using light pressure. Three (3) consecutive measurements will be taken on your left or right cheek on an area with visible hyperpigmentation at the Baseline (before product application), Week 10, and Week 18 timepoints.

Expert Grading
You will be asked to close your eyes while a technician examines your skin using a lighted, magnified lens. The technician will be assessing your skin's hyperpigmentation, brightness/radiance, and skin texture (visual only) at the Baseline (before product application), Week 10, and Week 18 timepoints.

VISIA-CR Imaging
Photographs will be taken in a controlled environment by a professional photographer or trained technician. You will be asked to wear a headband for consistency, however no other restraining devices or invasive equipment will be used. You will stand in a neutral position and insert your head into the VISIA-CR capture enclosure (like a photobooth, see photograph.). A black cape will be placed around your shoulders in the front so clothing or reflections will not be visible. The photographer/trained technician will guide you through the process and explain each procedural step required for efficient study

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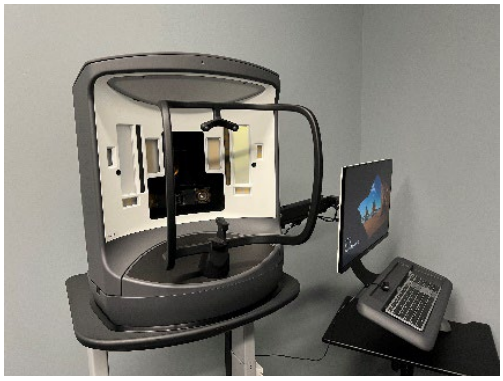
completion. Photographs will be taken at the Baseline (before product application), Week 10, and Week 18 timepoints.



Subjective Questionnaire

You will be asked to answer questions regarding your level of agreement with statements about the product's performance. Using your mobile telephone, you will receive a text message with a link (or you may scan a QR [a type of bar code] code to access and complete the questionnaire online via Datacapt at the Week 18 timepoint.

**POTENTIAL RISKS**

The study product(s) is for external use only and must be used only by the person enrolled in the study. Do not share the product with anyone else. Possible side effects/allergic reaction may include redness, dryness, itching, rash, irritation, burning, or infection. These reactions may occur on or near the application area but could also appear elsewhere on the body. If you have a history of sensitivity to skincare or cosmetic products, you should not participate in this study. Some risks may be unknown at this time. If new information that might affect your decision to continue participating becomes available during the study, you will be informed. There is a potential risk of loss of confidentiality when photographs are taken for study documentation. Some evaluations are performed in a group setting which may also lead to a loss of confidentiality. All efforts will be made to protect your privacy. The devices/instruments used in this study are non-invasive and have no known risks associated with them. It is recommended that you wash your hands before and after applying the test product(s) and support product(s)-if applicable. Avoid contact with eyes. If any product comes in contact with your eyes, rinse thoroughly with cool water. If irritation or a reaction occurs, stop using the product and contact the Study Coordinator immediately.

**(Chrystal Planeta, phone number 201-331-9400)**

In the event of a medical emergency, you should seek medical attention first and then contact VCS. If you receive any medical care during the study, inform medical personnel about your participation in a clinical research study. Please provide VCS with an update on your condition. If you experience an injury as a direct result of administration of the study product, the study sponsor agrees to pay medical expenses necessary to treat such injury:

1. To the extent you are not otherwise reimbursed by your own medical insurance.

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2. Provided you have followed the directions of the investigator before and after the injury occurred. Additional financial compensation will not be provided. Medical follow-up will be provided until the investigator or study coordinator determines you have recovered.

**BENEFITS**

As a result of participating in this study, you may experience an improvement in skin's hyperpigmentation, brightness/radiance, and skin texture or you may experience no benefit at all.

**COMPENSATION**

| | |
|---|---|
| Visit 1- Screening Visit | $25.00 |
| Visit 2- Baseline Visit | $75.00 |
| Visit 3- Week 10 Visit | $200.00 |
| Visit 4- Week 18 Visit | $200.00 |
| **Total Payment** | **$500.00** |

You will be paid via a reusable debit card. Funds will be available approximately 2 business days after the final study visit.

If you qualify at the Baseline visit but are not enrolled due to overbooking, you will receive $25.00. Overbooking is standard VCS practice due to frequent cancellations and no-shows.

If you do not qualify for the study, you will not be compensated.

If you are discontinued from the study for reasons unrelated to your behavior (e.g., medical concerns, adverse effects [unfavorable or unintended medical occurrence]), you shall receive partial payment for the visits you completed.

If you are disqualified for not following instructions, missing visits, or failing to comply with study rules, you shall receive partial payment for the visits you completed according to study rules included in this Informed Consent.

No exceptions will be made to issue total payment before study completion. You may withdraw from the study at any time without penalty. VCS or the study sponsor may also discontinue your participation at any time without your consent.

Full payment will only be provided after:

- All scheduled visits are completed
- Product and daily log are returned (payment will be held until these are returned to VCS)
- You are determined to be compliant (all visits, procedures, and questionnaires completed) with the study requirements.

WAIVER OF HARM OR LOSS

By signing this form, you agree to defend and hold harmless VCS, the company contracting this study, their affiliates, and their respective equity holders, directors, officers, employees, principal investigator, research staff, and agents from and against any and all claims (including, but not limited to actions, causes of actions, judgments, losses, liabilities, data breach, damages, property damages, expenses,

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attorney's fees, court fees, interest, penalties, research-related injury, illness, or death) relating to or arising out of your participation in this study and your exposure to the study products and procedures.

You are not obligated to defend or hold harmless VCS, the company contracting this study, their affiliates, and their respective equity holders, directors, officers, employees, principal investigator, research staff, and agents for any claim arising out of gross negligence or a more culpable act or omission, including recklessness or willful misconduct.

**PANELIST RIGHTS & CONFIDENTIALITY**

All personal and medical information collected during this study will be kept confidential by Validated Claim Support (VCS). Records are coded to protect your identity. Except in cases of medical emergencies or adverse events, your information will be handled in accordance with HIPAA (Health Insurance Portability and Accountability Act of 1996) and FDA (U.S. Food and Drug Administration) privacy regulations. Your information may be shared only with authorized VCS staff, the Institutional Review Board (IRB), and a consulting physician, if necessary. Study sponsors will not have access to your personal identifiers such as your name or medical history, but de-identified data from this study may be shared with the study sponsors and the research community to help advance science. The de-identified information might be used for future research without your additional consent. By signing this form, you authorize VCS to use and share your information as described above for the purposes of conducting and monitoring this study.

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**USE OF PERSONAL INFORMATION (HIPAA) AUTHORIZATION**

Your participation in this study requires sharing certain personal and medical information with Validated Claim Support (VCS). This may include your name, contact details, Social Security Number, demographic information (such as age, sex, race, and occupation), and relevant medical history (such as allergies, medications, or conditions). A Study Coordinator, Investigator, or authorized staff member may collect this information from you. By signing this form, you authorize VCS to access and use your medical records for any treatments, illnesses, or injuries that occur as a direct result of using the test product. This information will only be reviewed by VCS staff who are responsible for conducting and reporting on the study and who have signed confidentiality agreements. Your identifiable information will never be published in any report. However, regulatory agencies such as the FDA, or the Institutional Review Board (IRB) may review your records for oversight purposes. VCS may also store your medical information in a secure database to contact you about future studies. This authorization does not expire, but you may revoke it at any time in writing, unless VCS has already used the information for this study. Upon request, VCS will no longer contact you for future studies. VCS does not sell or share your identifying information.

Your signature below indicates you have read the above privacy statement.

| **Signature** | **Date (DD/MMM/YYYY)** |
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**CONSENT**

❒ I confirm that I received a physical and/or electronic copy of this Informed Consent, had enough time to review it, and was given an opportunity to ask questions. A VCS staff member explained the study to me before I signed this form.

❒ I have read and understood this informed consent form and voluntarily agree to participate in this clinical research study. I may choose not to participate or may withdraw at any time without penalty. I acknowledge that VCS will keep records of my participation for compliance purposes.

If you have questions about your rights as a research participant, you may contact the Institutional Review Board (IRB):

**Allendale Investigational Review Board**
Phone: 860-434-5872
Email: subjectrights@allendaleirb.com

**ELECTRONIC SIGNATURES**

Signing this document and any related study forms electronically using a secure platform such as Datacapt is legally valid and has the same effect as a handwritten signature. The system used meets applicable legal and regulatory standards to ensure your consent is secure, verifiable, and protected.

Participant Signature
Purpose: Voluntary Informed Consent to Participate

VCS Representative Signature
Purpose: Verification of Informed Consent Form and Process Completion

| **Study Participant Print: First and Last Name** | **VCS-ID** |
|---|---|
| **Study Participant Signature** | **Date (DD/MMM/YYYY)** |

| **VCS Personnel Print: First and Last Name** | |
|---|---|
| **VCS Authorized Witness Signature** | **Date (DD/MMM/YYYY)** |