Participants' Information Sheet

Introduction:

This study will assess the cosmetic changes of cosmetic topical products utilizing non-invasive skin imaging instrumentation. The properties of the skin, in the form of firmness, elasticity, and other skin surface parameters, will be analyzed.

Scope of the study:

Participants will be selected based on respondents to blog posts, flyers, and advertisements posted online and on local community notice boards. Volunteers will be randomly split into groups to participate in a study.

This study will be held at LSR Ltd and will run for anywhere between 2 weeks and 4 months. The study will commence on a weekday and will conclude on a weekday.

The test site can be on area of the body. Commonly, we test cosmetic products on the face, inner forearms, hands, neck, etc. Specific instructions will be sent out for each study. Participants will be requested not to use any other topical creams on the test sites during the study.

Sometimes, a study could be a Patch test study or may include a patch test. To carry out the Patch test, you will have to wait in a temperature- and humidity-controlled conditioned room for 20 minutes (with your forearms exposed/sleeves rolled up) to allow your skin to acclimatize to the room's conditions. Measurements will then be taken, which will require 25 minutes to complete the measurements of the test sites (giving a total of 45 to 60 minutes per visit).

Type of Research:

This is an intervention study. We aim to study the efficacy of cosmetic products provided to human participants for the purpose of adding knowledge to the efficacy and how well the skincare products work.

During this study, you will be required to arrive at our premises (at a day and time to be advised) and have the skin test site measured for different parameters (e.g., wrinkle depth, firmness, elasticity, etc.). You may also have a patch test done, be asked to follow a strict routine (e.g., cleanser in the morning and evening, moisturizer in the morning and evening, and sunscreen in the morning and as needed, etc.), and given instructions on method application (rub, dab, spray, etc.), frequency of application (overnight, all day, throughout the day, rinse-off, etc.), and total skin contact (forearm, face, etc.). This will be explained in-depth in your Guidance notes.

Participant Selection:

The inclusion criteria for each study will be disclosed. We welcome healthy participants who are both available and eligible (eligibility differs from study to study). Participants are also required to be fluent in the English language, as no interpreter will be made available.

The exclusion criteria for any study will be made available for each study. Please contact LSR Ltd. (*contact details at the bottom of this* document) to find out if you qualify before the study commences.

Voluntary Participation:

Your participation in the study is entirely voluntary (your choice). You do not have to take part in this study. If you do take part in this study, you are free to withdraw at any time, without having to give a reason. Your participation will be stopped if any harmful effects appear.

Side Effects:

We receive safety assessment documents with each product we test. This document guarantees the safety of the product(s) on human participants. It is also common practice to test products that have been on the market for several years. Some of these products have not posed any known risks, health or otherwise, to customers. We therefore deem our studies low to no risk.

However, to minimize any risks, participants may undergo a patch test, and be educated on method of application (e.g., spray, rub, dab, etc.), duration of application (e.g., overnight, rinse-off, etc.), frequency of application, total skin contact, etc. Furthermore, upon the unlikely event of any side effects (e.g., reddening, itchiness, swelling, etc.), participants will be directed to discontinue use and report event. Participants will be instructed on what to do in the event of an emergency.

Inconveniencies:

To ensure accurate skin measurements are taken, you:

1. may be asked to shave or wax the test site (e.g., forearm) (ONLY IF your hand hair is coarse and/or dense).
2. are required to comply with the instructions for applying the products.
3. are required to record your application in the Diary sheet provided. Should you miss an application, please notify LSR *(contact details at the bottom of the document) as soon as possible*, and we will discuss how to proceed. This does not mean withdrawing from the trial.
4. are NOT allowed to consume carbonated drinks, teas, or coffee an hour prior to testing.

Risks:

We do not expect this but as everyone's skin is different, you may experience any one or more of the following.

1. Your skin may be dry, flaky, itchy and/or appear red on the test site. This may persist for over a week for some volunteers and should resolve on its own. If this does not resolve, please discontinue use, and notify LSR immediately *(contact details at the bottom of the document).*

2. You may have a reaction to the products. In this case, rinse test site with cold water (do not rub vigorously), discontinue use of products, and notify LSR immediately *(contact details at the bottom of the document).*

3. Your eyes may be irritated (reddening, itchy, teary) upon contact with our products. Please do not apply products close to your eyes, or on your eyelids. Should this happen, rinse out with cold water, and pat dry.

Benefits:

While we make no representations and provide no guarantees that you will obtain any direct or indirect health benefits from participating in this study, it is possible that some participants may observe or experience improvements in the hydration or suppleness of their skin and/or a reduction in the visible signs of aging or skin damage in the area of skin applied to under the study protocol.

You will also find out and learn more about the characteristics of your skin in general, and better understand how hydrated/dry, smooth/rough, supple/scaly your skin naturally is.

Commitment, Cost & Compensation:

You will not incur any costs for participating in the study.

We appreciate your participation in the study, and as a gesture to thank you for your time and efforts, you will receive a gift voucher at the end of every visit. The amount will vary depending on the study, and will be made public on all ongoing studies. There is no other compensation for your participation in this study.

Loss and Damage:

We have asked you to participate in this study to help us assess the efficacy of a product. It is up to you to decide if you would like to assist us. In doing so, you will be agreeing and acknowledging that LSR is not responsible or liable to you in any way for any costs, losses, damages, personal injury or any other claim that may arise; whether directly or indirectly. Neither will you be eligible for cover under accident compensation legislation. If a volunteer suffers injury as a result of the trial itself, they may not be eligible for cover under accident compensation legislation. However, compensation may be provided in accordance with the "New Zealand Researched Medicines Industry Guidelines on Clinical

Trials – "Compensation for injury resulting from participation in Industry Sponsored Clinical Trials".

These RMI Guidelines are only guidelines and, until your claim is assessed by the insurers of LSR Limited, it cannot be said with any certainty exactly what type or amount of compensation you will receive if you suffer injury as a result of your participation, or what sort of injury will be covered. The guidelines require that compensation must be provided by LSR Limited where the injury you suffer is serious and not just temporary and is one where you would not have suffered injury but for your inclusion in the trial.

The guidelines also require that the compensation you receive must be appropriate to the nature, severity and persistence of your injury. This means that you will be likely to receive some compensation from LSR Limited unless your injury is minor or temporary, however, you might not receive compensation from LSR Limited if your injury was caused solely by you.

Ownership Rights

Information from this study may lead to discoveries or enhancements in the development of a commercial product. The rights to these will belong to the sponsor of the study. You will not receive any financial benefits or compensation, and will not have rights in any developments, enhancements or other discoveries that might come from this information.

Confidentiality:

No material that could personally identify you will be used in any reports on this study. Volunteers will be assigned a number, and information connecting the assigned number to the participant will be held confidentially by the principle researchers and technicians.

Records from this study will be securely held on a computer server with access by the principle researcher and two additional staff members only. Additional access to this server requires the written permission of the Clinical Trials Scientist.

Rights to Access Your Information:

You have the right to request access to your information held by the research team. You also have the right to request that any information be updated or amended.

Results:

A summary of your results of this study will be made available to participants upon request. Please feel free to contact LSR *(contact details at the bottom of the documents)* if you have any questions about this study.

Approval:

Even though this study does not require ethics committee approval because it does not involve the administration of our products for a therapeutic purpose and is not a health and disability research, we have received an out-of-scope letter from the HDEC.

Please feel free to contact the investigators if you have any questions about this study.

Consent & Copies for your Record:

We welcome your participation in this study. If you would like to proceed and agree to take part, please complete, sign and submit the applicable Consent Form.

A copy of both this Information Sheet and your completed Consent Form will be provided to you for your records.

Right to Refuse or Withdraw:

This is an optional study. You do not have to take part in this study. If you do take part in this study, you are free to withdraw at any time, without having to give a reason.

In the unlikely event that there are any concerns with your Consent Form, your safety, any logistical issues or any other practical matter, we reserve the right in our sole discretion, not to progress with your participation in the study at any time by providing notice to you.

Emergency Contact

LSR Limited

02102001170

trials@livingskinresearch.com

Dr Tinu Odeleye

NZ Med helpline

0800 611 116