

**MALIBU WELLNESS, INC.**  
**CLINICAL RESEARCH CONSENT FORM**

Researchers: Asim Rustamov, M.D., Clinical Research Manager  
Tom Porter, M.S., President

Malibu Wellness, Inc. is conducting a study and appreciates your participation. The purpose of this consent form is to provide you the information regarding your participation. Please read the form carefully and inquire from the researcher any questions that you may have after reading this document. When all your questions have been answered, please sign at the end of the document. This process is called ‘informed consent.’

**PURPOSE OF THE STUDY**

The purpose of this study is to document the effects of certain ingredient compounds on various skin conditions.

The findings and documentations of this clinical study, and/or information recorded during the course of the study are not intended nor can in any way be considered a diagnosis of a medical condition.

**STUDY PROCEDURES**

The study involves recording a photographic image of the affected area of skin by a specific device, called SIAscope. This non-invasive method of documentation uses the SIAscope to produce a picture as a result of placing the hand-held device to the surface of the skin and then scanning the affected area. This method allows the researchers to record the average amounts of blood, collagen and pigment in the recorded area.

Participants are provided certain ingredient compounds and are instructed to use on the documented affected areas of the skin two (2) times a day for a total period of three months. The participants must undergo the SIAscope imaging process immediately prior to the first time application of such ingredient compounds and repeat the re-evaluation of their skin conditions at time intervals agreed upon with the researcher.

**BENEFITS OF THE STUDY**

Our intent is to determine if various ingredient compounds can help individuals to improve the appearance and soothe various skin conditions. You will receive the ingredient compounds at no cost to you and the results of your participation in this study will be available for you and your care provider at no charge to you. You will not receive any financial compensation or reimbursement of any expenses incurred by you as a result of your participation.

**ALTERNATIVES TO PARTICIPATING IN THIS STUDY**

Participating in this study is voluntary. If you choose to discontinue your participation after beginning this study, please inform Malibu Wellness, Inc. in writing, describing the reason for withdrawal as this information could be helpful to the conclusions of this study.

**INFORMATION and CONFIDENTIALITY**

The information collected includes four images of the affected area of your skin and any medical information provided to us by you or your medical care provider. Malibu Wellness, Inc. desires to provide any information as a result of this study to your personal medical care provider. Malibu Wellness, Inc. also desires to receive any diagnosis, treatment and/or related information from your medical care provider about the specific affected area of skin being documented in this study.

Respective of the *Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule*, any information received by Malibu Wellness, Inc. will never be used in association with your name or personal identity without your written permission. The link between your name and the data obtained about your skin or health condition will only be accessible to the President and Clinical Research Manager.

It is understood that any reference, use or replication of the data collected will not include any reference to your identify. Malibu Wellness, Inc. retains the right to use any and all information obtained from you and about you for its own purposes, provided that this information will not be linked to your name or be linked to your identity. This information may be used and/or reviewed by organizations including but not limited to: Institutional Review Boards, your physician/dermatologist, state and/or federal regulators, and Malibu Wellness, Inc,

\_\_\_\_\_  
Signature of investigator

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Date

Participant's statement

This study has been explained to me and I have no additional questions regarding the study or use of the findings. I volunteer to participate in this research. I have had a chance to ask questions. If I have questions in the future about this research, or my rights as a participant, I will ask one of the researchers listed above by calling the Clinical Trials Department at 1(800) 622-7332 ext. 301. I give my permission for the researchers to use my medical records, as well as information obtained about my skin condition(s) without linking them to my identity, as described in this consent form. I will receive a copy of this consent form.

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Date

Participant's telephone number: \_\_\_\_\_

Copies:      Subject  
                  Investigator's file