Sub-Epidermal System Innovative Care, Inc.

Clinical Research Consent Form

Sub-Epidermal System Innovative Care, 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 Sub-Epidermal System Innovative Care, Inc. Clinical Team any questions that you may have after reading this document. When all your questions have been answered, please sign at the end of this document. This process is called 'informed consent'.

PURPOSE OF STUDY

The purpose of this study is to provide safe and effective hair removal to eligible participants who have a documented history of failure with hair removal. These studies will record and document any findings that will support through photographic images, the photos will show the immune system is strengthened. Upon written request the findings will be available to the medical care provider.

STUDY PROCEDURE

Sub-Epidermal System Innovative Care, Inc. study procedure involves recording your current and past history in writing that includes real-time data. The study involves taking before and after photographic images of specific hair areas. The non-invasive method of documentation uses needle applications that never exceed the confines of the hair follicle.

THE STUDY WILL PROVIDE

Our intent is to provide documented data for early detection. You will receive validation of safe and effective methods for hair removal. This study will be provided at no cost to you. You will receive an initial consultation prior to study and a follow-up assessment preceding the end of the study. You will not receive any 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 Sub-Epidermal System Innovative Care, 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 photographic images of specific hair areas and any related information provided to us by you or your medical care provider**.** Sub-Epidermal System Innovative Care, Inc. desires to provide any information as a result of this study to your personal medical care provider. Sub-Epidermal System Innovative Care, Inc. also desires to receive any findings, treatment and/or related information from your medical care provider about the specific area of hair being documented in this study.

Respective of the *Health Insurance Portability and Accountability Act of 1996 (HIPA) , Privacy Rule*, any information received by Sub-Epidermal System Innovative Care, 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 hair or associated condition will only be accessible to the Director, and Clinical Research Team.

It is understood that any reference, use or replication of the data collected will not include any reference to your identity. Sub-Epidermal System Innovative Care, 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 Sub-Epidermal System Innovative Care, Inc.

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Signature of Director Printed Name Date

<u>Participants Statement</u>

This study has been explained to me and I have no additional questions regarding the study or the use of the findings. I volunteer to participate in this research. I have had a chance to ask questions. If I have any questions in the future about this research, or my rights as a participant, I will ask one of the researchers by contacting Sub-Epidermal System Innovative Care, Inc… at (201) 788-0096. I give my permission for the research to use my medical records, as well as information obtained about my hair condition(s) without linking them to my identity, as described in this consent form. I will receive a copy of this consent form via mail, email, and/or in person at the time of my initial consultation.

_____ _____ _____

Signature of Participant Print Name Date

Participants Telephone#: ( ) _____-_____