ALBERT EINSTEIN COLLEGE OF MEDICINE
MONTEFIORE MEDICAL CENTER

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called **Efficacy of Silicone Gel versus placebo for post-surgical scars of the eyelids.** Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." Her name is Dr. Anne Barmettler. You can reach Dr. Barmettler at:
3332 Rochambeau Avenue
Centennial building, 3rd floor
Bronx, New York
Telephone #: 718-920-2020
For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253, by e-mail at irb@einstein.yu.edu, or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002
Bronx, New York 10461

Why is this study being done?

Our study is designed to determine whether topical silicone may prevent significant post-operative eyelid scar formation. The study may help clarify whether there is a safe and effective topical treatment for patients undergoing eyelid surgery for whom scarring or cosmesis is a concern.

We also want to find out if topical silicone is safe to apply without causing too many side effects.

The study drug, ScarAway silicone gel is an over-the-counter medication, regulated by the U.S. Food and Drug Administration (FDA) to treat skin scars.

Why am I being asked to participate?

You are being asked to participate in this study because you have a medical condition called blepharoptosis (droopy eyelids), for which you are undergoing surgical repair by Dr. Anne Barmettler. Pregnant women, nursing women, and patients under the age of 18 are excluded. A total of 100 people will be enrolled in this study. This is a single-site study (no other sites are included).

How many people will take part in the research study?

You will be one of about **100** people who will be participating in this study.

How long will I take part in this research?

It will take you about 6 months to complete this research study. During this time, we will ask you to make 6 monthly post-operative study visits to Montefiore Medical Center.

What will happen if I participate in the study?

After your surgery, all participants will receive 2 tubes of medication, one containing ScarAway silicone gel (the study drug) and the other, a simple emollient, without any drugs, (the placebo). We will randomly (like a coin toss), assign you to always use the study drug on one side of your face (left or right) and always use the placebo on the other side.
You and the study doctor cannot choose which side of your face will receive the study drug. The contents of both tubes look exactly alike, so neither you nor your doctor will know which tube contains the study drug. Nonetheless, the tubes will be clearly identified so you know which side of your face each is to be applied.You will be asked to apply the assigned topical creams to each post-operative eyelid scars twice daily for 6 months.

You will be asked to make 6 monthly post-operative visits. Each will take about 20 minutes. At each visit we will:

- Ask you about side effects or health problems since your last visit
- Give you some questionnaires to fill out
- Take a close-up photo of each of your eyelids
- Give you a new supply of study medications if needed

The study is being conducted in this way to allow us to get an unbiased look at the experience and effect of using the study drug.

As part of this study we will review your medical records and put the information we collect in our research records.

Information Banking (Future Use and Storage)

We will store information about you in a “bank”, which is a library of information from many studies. This information cannot be linked to you. In the future, researchers can apply for permission to use the information for new studies to prevent, diagnose, or treat disease, including genetic research. Your information may be kept for a long time, perhaps longer than 50 years. If you agree to the future use, some of your de-identified genetic and health information (not linked to you) may be placed into one or more scientific databases. These may include databases maintained by the federal government.

You can choose not to participate in the bank and still be part of the main study and this will not affect your treatment at this facility.

INITIAL ONE (1) OF THE FOLLOWING OPTIONS
_____ I consent to have my information used for future research studies.
_____ I do NOT consent to have my information used for future research studies.
Information about me will be kept as long as required by regulations and institutional policy,

but will not be used for future studies.

Will I be paid for being in this research study?

You will not receive any payment or other compensation for taking part in this study.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your specimens and information or for any tests, treatments, products or other things of value that may result from the research.

Will it cost me anything to participate in this study?

Taking part in this study will not involve added costs to you. All study drugs will be given free of charge by the sponsor, company or the drug makers. You and/or your insurance company will have to pay for any costs that are part of your regular medical care.

What will happen if I am injured because I took part in this study?

If you are injured as a result of this research, only immediate, essential, short-term medical treatment as determined by the participating hospital, will be available for the injury without charge to you personally.

- No monetary compensation will be offered.
- You are not waiving any of your legal rights by signing this informed consent document.
- If additional treatment is required as a result of a physical injury related to the research, necessary medical treatment will be provided to you and billed to your insurance company or to you as part of your medical expenses.

Immediately report any discomforts, problems or injuries you experience during the course of your participation in the study to Jose Rosado, Clinical Research Administrator, 718-920-5198.

What else do I have to do?

- You must tell the research study doctor about any past and present diseases or allergies you are aware of and about all medications you are taking including “over-the-counter” remedies and nutritional supplements or herbs.
- You must use your study medications as instructed, returning any unused medication (including any empty or partly used tubes), at every visit.
- If you do not feel well at any time call your doctor or the research study doctor immediately.
- If you have any questions about your experience with the study medications, please call the research study doctor promptly.
- If you think you have become pregnant, contact your research study doctor immediately.
- If any other doctor recommends that you take any medicine, please inform him/her that you are taking part in a research study. You should give the other doctor the research study doctor’s name and phone number.
- You may carry out all your normal daily activities.

Confidentiality

We will keep your information confidential. Your research records will be kept confidential and your name will not be used in any written or verbal reports. Your information will be given a code number and separated from your name or any other information that could identify you. The form that links your name to the code number will be kept in a secure manner and only the investigator and study staff will have access to the file. All information will be kept in a secure manner and computer records will be password protected. Your study will be kept as long as they are useful for this research.

Medical information collected during the research, such as test results, may be entered into your Montefiore electronic medical record and will be available to clinicians and other staff at Montefiore who provide care to you.

The only people who can see your research records are:

- the research team and staff who work with them
- the organization that funded the research
- groups that review research (the Einstein IRB, and the Office for Human Research Protections

These people who receive your health information, may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them. All of these groups have been asked to keep your information confidential.

Are there any risks to me?

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy – see the Confidentiality section above for details.

There is a risk that applying the topical silicone gel (the study drug) will cause skin rash, and/or itching. Although it is rare, some people experience similar symptoms from the emollient (placebo). It is possible that your experience with the 2 study medications could be different.

Allergic Reaction to Study Drug

Any drug can cause an allergic reaction which could be mild or more serious and can even result in death. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat, or trouble breathing. If you are having trouble breathing, call 911 immediately.

New Findings

If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

Unknown Risks

We have described all the risks we know. However, because this is research, there a possibility that will have a reaction that we do not know about yet and is not expected. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to be in the study.

Are there possible benefits to me?

You will not experience any direct benefit personally from participating in this study. We hope you will participate because the study will generate important information about minimizing post-surgical facial scars.

What choices do I have other than participating in this study?

You can choose not to participate in the study. If you decide not to participate, the medical care providers at this facility will still give you all of the standard care and treatment that is appropriate for you.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility. However, some of the information may have already been entered into the study and that will not be removed. The researchers and the sponsor may continue to use and share the information they have already collected.

To revoke (take back) your consent and authorization, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or

take back your consent and authorization, you will not be allowed to continue to participate in this research study.

Can the study end my participation early?

We will not let you participate in the study any more if you develop prominent scarring of either eyelid. In addition, your participation will end if the investigator or study sponsor stops the study earlier than expected.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant	Date	Time
Printed name of the person conducting the consent process	Signature	Date	Time