COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY
YALE UNIVERSITY SCHOOL OF MEDICINE
YALE-NEW HAVEN HOSPITAL

Study Title: **Assessing a Natural Product plus Bioadhesive Nanoparticle (BNP) Sunscreen**
Principal Investigator (the person who is responsible for this research): Michael Girardi, MD, LMP 5040
Phone Number: 203 785 7432

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to evaluate the effects of a new sunscreen formulation.
- Study procedures will include: **Eligibility screening, consent, physical examination of skin, application of sunscreen, ultraviolet exposure of skin, five skin biopsies**
- **Four** visits are required.
- These visits will take **1-1/2 to 2** hours total.
- There are some risks from participating in this study. **Skin irritation, sunburn to exposed areas of skin, bleeding, skin infection and small scar at skin biopsy sites.**
- The study may have no benefits to you. **Participation in this study will enable the development of a safer, more protective UV sunscreen that may benefit individuals across multiple communities.**
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Why is this study being offered to me?
We are asking you to take part in a research study because your skin type is sensitive to UV exposure. We would like you to help us test the effectiveness of a new natural product bioadhesive sunscreen. This new sunscreen has a special coating that forms a small capsule around the sunscreen filters to keep the sunscreen on the outside of your skin. Current sunscreen products are absorbed into your skin. We are looking for 30 participants to be part of this research study.

Who is paying for the study?
This study is funded by the Yale SPORE in Skin Cancer Grant from the National Cancer Institute (NCI).

Who is providing other support for the study?
No other support is being provided.

What is the study about?

The purpose of this study is to test a new natural product bioadhesive nanoparticle sunscreen that we have developed. We hope to create a safer, non-toxic, longer lasting sunscreen that will help prevent damage to human skin when it is exposed to the sun.

What are you asking me to do and how long will it take?

If you agree to take part in this study, this is what will happen:

Before you can enroll in the study, we will need to confirm your eligibility. To be eligible, you must be at least 18 years old, and you cannot have a history of skin cancer (such as basal cell carcinoma, squamous cell carcinoma, or melanoma); and you cannot have a history of skin disease (such as psoriasis, eczema, lupus, dermatomyositis or vitiligo). You cannot have a family history of melanoma. If you are a woman of childbearing potential, pregnancy testing will be required before you may be enrolled in the study.

In addition, your skin type must be I, II, or II on the following scale:

- Skin Type Characterization and Sunburn/Tanning History:
    - Based on first 30 to 45 minutes sun exposure after a winter season of no sun exposure, under which category would you characterize yourself:
      I--Always burns easily; never tans (sensitive).
      II--Always burns easily; tans minimally (sensitive).
      III--Burns moderately; tans gradually (light brown) (normal).
      IV--Burns minimally; always tans well (moderate brown) (normal).
      V--Rarely burns; tans profusely (dark brown) (insensitive).
      VI--Never burns; deeply pigmented (insensitive).
- You will also be asked to provide a brief medical history with emphasis on the effects of sunlight on your skin. To be eligible, you cannot be using any medications that are known to make you more sensitive to sunlight.
- We will perform a test site inspection. The physical examination shall determine the presence of sunburn, suntan, scars, active dermal lesions, and uneven skin tones on the areas of the back to be tested. The presence of nevi, blemishes, or moles will be acceptable if they will not interfere with the study results.

If you are deemed eligible and choose to voluntarily participate in this study, you will be asked to complete the following:

Visit 1: Participants will first visit the study site for screening, informed consent, and a physical examination with comprehensive medical history. If eligibility requirements are met, the research personnel will identify one area of your skin for the evaluation of your minimal erythema dose (MED). (MED is the shortest exposure to ultraviolet radiation that produces reddening of the skin within 1 to 6 hours and disappears in 24 hours.) This area will then be exposed to ultraviolet light that is similar to the sun's rays. You will be asked to return to the study center the next day, approximately 16 to 24 hours later, for more testing and skin biopsies. If you are a woman of childbearing potential, a urine pregnancy test will be given before you proceed in the study.

Visit 2: Upon return the next day, your MED will be determined. The research personnel will then identify a 4 x 5.5 cm area on your inner upper arm that will be used for the testing of the sunscreen. Within this small area, four smaller areas will be identified. Two the areas will have the test sunscreen applied to them. The other two areas will not receive any sunscreen. After the sunscreen has been applied, you will be asked to rest for 15 minutes while the sunscreen absorbs into your skin. After the 15 minutes have passed, all four areas will then be exposed to

the ultraviolet light. The time your skin is exposed to the ultraviolet light will depend on the results of your MED testing from Day 1 / Visit 1. Immediately after the ultraviolet exposure is completed, Dr. Michael Girardi will take three small (3 mm) skin biopsies from your skin. After these skin biopsies are completed, then you may leave the clinic area. You will need to return in 4 hours.

Visit 3: You will be instructed to return 4 hours after the ultraviolet exposure has occurred for two more small (3 mm) skin biopsies. After the skin biopsies are completed, you will receive instructions on how to take care of the skin biopsies. You will be given contact information for study personnel to call if you have any issues or questions about the biopsy sites. You will be given a date and time to return in 7 to 10 days for suture removal.

Visit 4: Suture removal (7 -10 days after Visit 3).

What are the risks and discomforts of participating?

As a participant of this study, you should be aware of the following foreseeable discomforts and inconveniences.

- Allergic reaction to the sunblock ingredients. This might cause a red itchy rash.
- Sunburn for unprotected control and some test sites after UV irradiation for SPF testing.
- Some of the complications associated with punch biopsy include local bleeding and bruising, pain, infection, allergic reaction to the numbing medicine used in the procedure, or damage to the structures beneath the skin site (such as an artery or a nerve). Your doctor will take care to reduce the likelihood of these rare problems
- To obtain additional information about the investigational sunscreen in the event of an emergency situation, please call Michael Girardi, MD and Kacie Carlson, PA-C at 203-785-7432 (Monday – Friday 9 am – 5 pm), 203 785 4445 (after hours / weekends).

How will I know about new risks or important information about the study?

We will tell you if we learn any new information that could change your mind about taking part in this study.

How can the study possibly benefit me?

You may or may not benefit from your participation in this study. But, you will be helping in the development of a safer sunscreen which will potentially decrease risk of skin cancers in the future.

How can the study possibly benefit other people?

Participation in this study may enable the development of a safer, more protective UV sunscreen that may benefit individuals across multiple communities.

Are there any costs to participation?

If you take part in this study, you will not have to pay for any services, supplies, study procedures, or care that are provided for this research only (they are NOT part of your routine medical care). However, there may be additional costs to you. These can include costs of transportation and your time to come to the study visits.

Will I be paid for participation?

You will be paid for taking part in this study. You will receive $200 upon completion of the study. This includes the initial visit, visit 2, 3 and 4 (as outlined above). You must complete the entire study to receive the $200. You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments

What are my choices if I decide not to take part in this study?

Because this investigation does not constitute treatment-based research, alternatives to participation would include not participating.

How will you keep my data safe and private?

We will keep information we collect about you confidential. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if you we learn that you are hurting a child or an older person.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission.

We will also share information about you with other researchers for future research, but we will not use your name or other identifiers. We will not ask you for any additional permission.

Your information and skin biopsies collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the researcher will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. Your responses/data will be de-identified upon collection. Post-processed research data will be stored on a password-protected computer. The research team will only give this coded information to others to carry out this research study. The link to your personal information will be kept for 3 years after which time the link will be destroyed and the data will become anonymous. The data will be kept in this anonymous form until it is destroyed.

What Information Will You Collect About Me in this Study?

The information we are asking to use and share is called “Protected Health Information.” It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Research study records
- Medical and laboratory records of only those services provided in connection with this Study.
- The entire research record
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research regarding
    - Physical exams of your skin
    - Medications you are taking
    - History of skin diseases
    - Personal and family history of skin cancer
    - Records about any study drug (sunscreen) you received
    - pregnancy test (females of child-bearing potential only)

How will you use and share my information?

We will use your information to conduct the study described in this consent form.
We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- The U.S. Food and Drug Administration (FDA) This is done so that the FDA can review information about new sunscreen involved in this research. The information may also be used to meet the reporting requirements of drug regulatory agencies.
- The study sponsor or manufacturer of study drug/device
- Drug regulatory agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- Health care providers who provide services to you in connection with this study.
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- Principal Investigator of the study, Dr. Michael Girardi
- Co-Investigators, Dr. Mark Saltzman, Study Coordinator and Members of the Research Team.
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study
    - Dr. Jeffrey Gehlhausen

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Why must I sign this document?

By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is

available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to ***Michael Girardi, MD*** at the Yale University, P.O. Box 208059, New Haven, CT 06520.

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to ensure the integrity of the study and/or study oversight.

Who will pay for treatment if I am injured or become ill due to participation in the study?

If you are injured while on study, seek treatment and contact the study doctor as soon as you are able.

Yale School of Medicine does not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.

What if I want to refuse or end participation before the study is over?

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

Not participating or withdrawing later will not harm your relationship with your own doctors or with this institution.

To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part.

The researchers may withdraw you from participating in the research if necessary. Conditions under which a subject may be withdrawn might include subject non-compliance.

What will happen with my data if I stop participating?

When you withdraw from the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to ensure the integrity of the study and/or study oversight.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator at **203 785 7432**

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

Conflict of Interest Declared by Investigators on this Study:
You should be aware that Dr. Girardi, principal investigator, Mark Salzman, PhD and Julia Lewis, PhD - co -investigators for this study, are named as co-inventors on a patent application covering the use of natural products in sunscreen, which is being tested in this protocol. They may have a potential financial interest in this research if it leads to the development of products that will be commercialized. If this happens, there is no plan to share any financial gain with you. You may speak with them at any time should you have questions regarding these investigator interests.

Authorization and Permission

Your signature below indicates that you have read this consent document and that you agree to be in this study.

We will give you a copy of this form.

Participant Printed Name	Participant Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date