

Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above.

Title of Research Study: A real-time, cost-effective, accurate UV measurement and sun protection system to prevent and reduce the incidence of sunburn in high-risk consumers. (SBIR R44, to Wearifi, Inc. R44CA224658-01)

Investigator: June K. Robinson, MD

Supported By: This research is supported by the National Institutes of Health.

Key Information:

The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are 18-80 years old and have a history of melanoma.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this study is find out about the ease of use of a wearable ultraviolet light (UV) sensor that registers sunlight exposure. The miniature sensor is about the size of a nickel and is worn clipped to a wristwatch, clothing or shoelace. The goal of this study is to prevent ultraviolet light overexposure and sunburns by providing people with relevant, easy-to-access, actionable information. The main benefit is becoming more aware of your sun exposure and protection habits.

How long will the research last and what will I need to do?

We expect that you will be in this research study for 25 days.

You will be asked to wear the sun sensor and transmit data to a provided android phone for 21 days. You will also be asked to complete a survey before you start wearing your sensor, each day you are wearing your sensor, and have an in-person exit interview at the Dermatology clinical offices at 645 N Michigan Ave. Suite 1050, Chicago, IL 60611. This study will require one to two visits to the Dermatology research offices. This study will also require that you allow us to send you daily text messages about wearing your sun sensor and sun protection tips. We expect that you will be in this research study for 25 days. The main benefit is becoming more aware of your sun exposure and protection habits.

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More detailed information about the study procedures can be found under the section “*What happens if I say “Yes, I want to be in this research”?*”

Is there any way being in this study could be bad for me?

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening.

Will being in this study help me any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include you becoming more aware of your sun exposure and protection habits

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Your alternative to participating in this research study is to not participate.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to Dr. June Robinson's research manager, Dalya, at 312-503-5918, Monday through Friday, 8 AM to 4 PM. Dalya can be reached by email at Dalya.abou-el-seoud@northwestern.edu

For technical issues involving the provided mobile phone, mobile application or sensor, please contact Simone Heo via email (preferred) at SeungHeo2013@u.northwestern.edu or at 217-649-8895.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 100 people here will be in this research study.

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What happens if I say “Yes, I want to be in this research”?

If you agree to participate, you will have an initial visit for about 30 minutes with a research assistant to provide you with an android mobile phone and the sun sensor. The research assistant will demonstrate how to access the application on the provided phone and show you how to properly wear and use the sun sensor, how to transmit data and how to receive text messages. An online questionnaire that is housed in Northwestern's security database, REDCap, will capture your contact information, demographics, and assess your knowledge about the sun's strength. For 21 days of the study, you will be expected to wear the sun sensor while awake and transmit data five times per day starting when you wake up in the morning, 10 AM, 2PM, 4 PM and bedtime.

Each day that you are wearing the sensor, you will complete an online survey about your sun protection. The survey will arrive in your email at around 6 PM.

At day ten, you will receive the same daily survey, but half of the study participants will receive the survey that has additional questions focusing on setting goals to improve sun protection behaviors. The other half will receive a free text box that allows for the writing of one's own sun protection goals. There is a 50/50 chance, like flipping a coin, as to what group you will end up in. You cannot choose which group you would like to be in.

Within 2-3 days of completing your 21 days of data transmission, you will return to the Chicago research office and have an interview, for about 30 minutes, with a research assistant or the research manager. This interview may be audio-recorded so that the study team may later transcribe the interview. You will be given the option to agree to the recording at the end of the consent form.

What happens if I say “Yes”, but I change my mind later?

You can leave the research at any time; it will not be held against you.

If you decide to leave the research, contact the investigator so that the investigator can obtain your permission to use any data collected, up until that point, to be used in research.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include you becoming more aware of your sun exposure and protection habits.

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What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings; for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial, [NCT03344796](https://www.clinicaltrials.gov/ct2/show/study/NCT03344796), will be available at <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

What else do I need to know?

If you agree to take part in this research study, we will pay you \$200 for your time and effort in the form of a gift card. You will be paid at the completion of the exit interview and once the provided android phone and sun sensor are returned to the research team. Parking will be validated, in full, if you will be driving to your last study visit.

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Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree

I disagree

The researcher may audio or video record me to aid with data analysis. The researcher will not share these recordings with anyone outside of the immediate study team.

The researcher may contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator of this study.

Signature for Capable Adult 18 or older

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

Signature of Participant

Date

Printed Name of Participant

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent