

Document Cover Page

Official Title of Study:

UV Exposure Assessed With Wearable Sensor and Sun Protection

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1.0 Purpose of the study:

Our goal is to prevent ultraviolet light (UV) overexposure by providing consumers with relevant, easy-to-access, specifically actionable information. This research proposal will develop a UV protection system consisting of an automated real-time counseling framework and a personal dosimeter that overcomes barriers to consumer adoption, with unmatched accuracy in real world conditions. These new, miniature sensors take the form of a small (< 1 cm), thin (< 0.1 mm), lightweight (< 0.1 g), battery-free spherical clip that is fundamentally differentiated from other wearable electronics in their modes of use, cost structures and accuracy.

Phase 1

Aim 1 will establish the accuracy of the measurements. Indoor tests using controlled light sources and outdoor measurements of UV insolation will determine calibration curves at different levels of irradiance and angles of incidence. Completion of this aim will yield accuracy $< 7\%$ at minimal erythema dose.

Aim 2 will develop a mobile application (app) for a prototype sunburn prevention system. The app will transfer deidentified data to the database and provide UV tolerances specific to the user's skin type. The app will collect user-reported outcomes of sunburn.

Ten adults aged 18-29 will assess the usability of the prototype and the mobile application. The results of the field test will serve as success criteria for phase 1: $> 80\%$ of users demonstrate proper use; and transfer de-identified data by near field communication to the database.

Phase 2

Aim 3 will assess the technology in a prospective cohort study in a high-risk population of 100 melanoma survivors aged 18-80. Extended (21 day) behavior studies of the one hundred individuals will determine compliance (target $> 85\%$) and user-satisfaction (target $> 70\%$ will continue to use). The result will confirm broad acceptability and efficacy in influencing healthy sun behavior.

Hypothesis: Participants will be able to confidently manage their UV exposure, and avoid sunburn.

Background / Literature Review / Rationale for the study:

No other carcinogen causes more cancer than excessive and unprotected exposure to ultraviolet (UV) light. Despite awareness of the risks, many Americans subject themselves to harmful levels of UV. Currently, it is burdensome to determine when personal exposure reaches harmful limits. Sunburn commonly serves as the only confirmation of overexposure. Sunburn is a preventable condition that is associated with increased risk for both non-melanoma skin cancer and melanoma, thus sunburn is an intermediate marker

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for development of skin cancer.^{1, 2} The rate of sunburn in the United States remains high, with recent data showing that 55.8% of American youths and 50.1% of adults aged 18-29 have experienced a sunburn in the prior year.^{1,3,4} Even so, the painful experience of sunburn or even the development of melanomas often do not provide sufficient motivation to change sun behavior.⁵ Wearable electronics can offer certain capabilities in UV monitoring, but the devices available today are expensive, physically obtrusive, and often incompatible with water recreation and sports.

The measurements involve intermittent determination of UV intensity, where total dosimetry follows from interpolative algorithms that result in poor accuracy under time variable exposure conditions. These shortcomings cause non-adoption, improper use or discontinuation, thereby limiting the prevention of overexposure, sunburn, and skin cancer. A broadly usable, low cost, accurate sun protection system that can influence healthy behavior represents a critical unmet need.

Combining a tiny personal, precision dosimeter the devices^{6,7} with behavioral strategies to enable sun protection will allow a direct-to-consumer approach to reach a population beyond physician counseling, as recommended by the US Preventive Services Task Force.⁸ Robinson et al demonstrated⁹ that text messages relevant to real-time activities increases sun protection behaviors among young children, and reduces changes in skin pigment (a biologic measure of effective sun protection). An accurate UV dosimeter that minimizes user burden paired with real-time messages triggered by user-specific UV exposure can promote broad-scale sun protection behavior in adults aged 18-29. Implementation will protect people who risk experiencing sunburn and ultimately reduce skin cancer incidence.

Relevant preliminary data

A pilot five-day clinical trial in a sunny environment that tested the devices measurement effectiveness in relation to reference devices including one designed for high precision scientific dosimetry (Scienterra) and a high end multi-purpose wearable consumer electronic (Microsoft Band). The study included fourteen subjects with multi-patch mounting on each (three patches on left arm; one on right arm), with some patches worn for several days and some patches removed for reapplication of a new one. Each reference sensor measures a single band of the UV light, one UV-A and one UV-B. Each skin-mounted patch measures both bands, UV-A and UV-B, separately.

The study included extended foot travel on the first day along a roughly 10 mile pre-defined path along four cardinal directions. The study also included days of normal activity in outdoor (beach) settings and city settings, with water exposure allowed only for segments of the trial in which the patients were not required to wear the Microsoft Band or Scienterra sensor to avoid malfunction of those devices. Water exposure (e.g. shower) was permitted with Wearifi body-mounted patches in place. Participants logged their activities and performed cell-phone data upload from bands periodically during mid-day segments of the study, once every one or two hours.

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Data from the same day of trial confirmed that the measurements by the skin-mounted UV dosimeter closely follows the measurements by the reference sensor (Scienterra). Figure 1 displays the data and portrays the measurement frequency used in the trial. The reference sensor uses battery power to perform a large number of instantaneous measurements. The UV patch of this proposal continuously accumulates photo-generated charge, uploads the data to smartphone, resets, and continues the accumulation. The two measurement schemes provide excellent agreement. The Wearifi sensor accomplishes it with inexpensive hardware and without batteries. The data presented here demonstrates the strong promise of the UV sensor as a product that consumers can use to accurately assess their UV exposure in real-time in order to practice sunlight avoidance with informed confidence. (Fig 1)

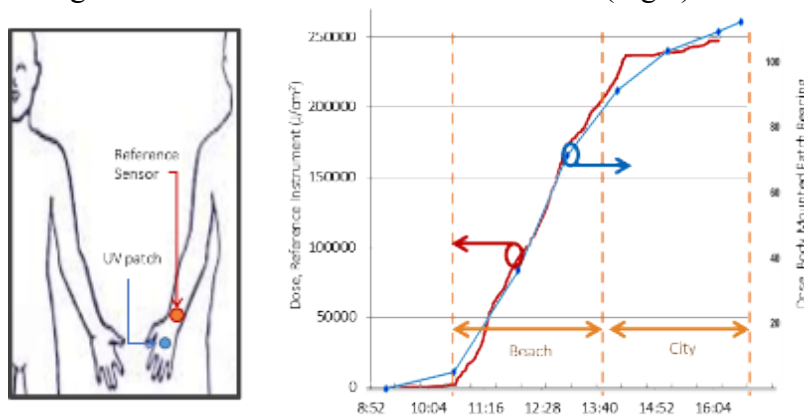


Fig 1. Comparison of UV dose measured by reference sensor and by UV patch. Significance of research/ innovation

The breakthrough innovation for this project is an electronic charge accumulation architecture applied to a tissue-mounted electronics platform developed by extensive multi-year research efforts in the John Rogers Research Group. The result is a miniaturizable UV dosimeter exceptionally suited to inexpensive miniature forms. Continued investigation has resulted in smaller, cost-reduced products with fully digital sensing capabilities.

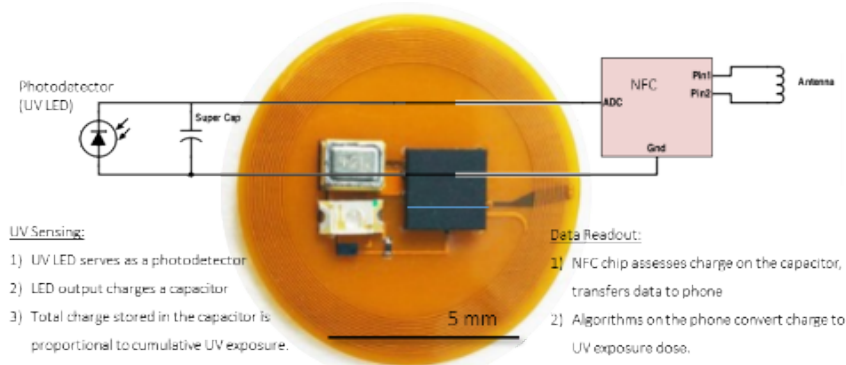


Figure 2: Device architecture using photo-charge accumulation from UV LED in body-mounted UV sensing patch (background).

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Figure 2 shows the device architecture, consisting of UV LEDs and supercapacitors, to provide accumulated dose measurements to the wearable NFC platform. The architecture uses off-the-shelf components in a proprietary and innovative way, providing a special opportunity for rapid scale-up with minimal investment in development. The scale bar of figure 2 further indicates the miniaturizability of the device.

Fig 3

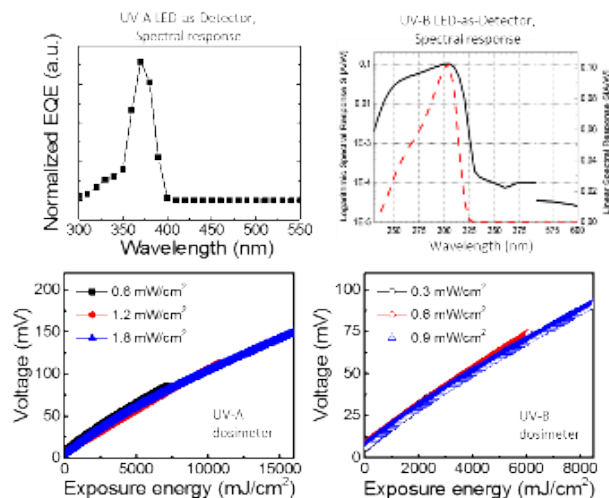
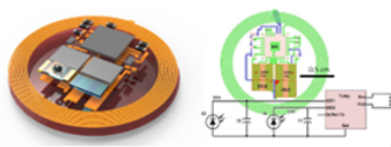


Figure 3 demonstrates the linearity and repeatability of UV-A and -B LEDs operating in the mode of UV sensor. UV dosimetry patches of the proposal can house both UV-A and UV-B monitoring components in a slightly larger device. Figure 5 shows schematics of such a device including a sample mounted on the back of the right hand and a simple demonstration of the device's response to separate sources of UV-A and UV-B. The UV-A source has wavelength peak of 365 nm, and the UV-B source has peak wavelength 300 nm. Acrylic adhesive secures the patch to the skin, and a thin coating of silicone encapsulates the device's circuitry from the environment, supplying water resistance.

Top Panel

UVA/UVB Digital Dosimeter Patch



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Middle Panel

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Figure 4: UV patch with digital dosimetry capabilities in UV-A and UV-B. Top panel left: 3D model; top right: physical layout and circuit diagram; bottom left: photograph of Wearifi sensor to be worn by participants; bottom right: response to monochromatic UV-A (365 nm) and UV-B (300 nm) light sources. Middle panel: clip device worn on a shirt. Lower panel: Outdoor UV dosimetry with multiple patches affixed to different faces of a box show the suitability of the patches for extended durations of measurement before data upload in a day-long trial described by figure 6. This demonstration also shows the utility of the miniature patches for multi-site application on a subject—a potentially important characteristic for reliably forecasts of a consumer's overexposure risk. For example, the east- and south-facing patches measured higher doses of UV exposure than the patch facing north.

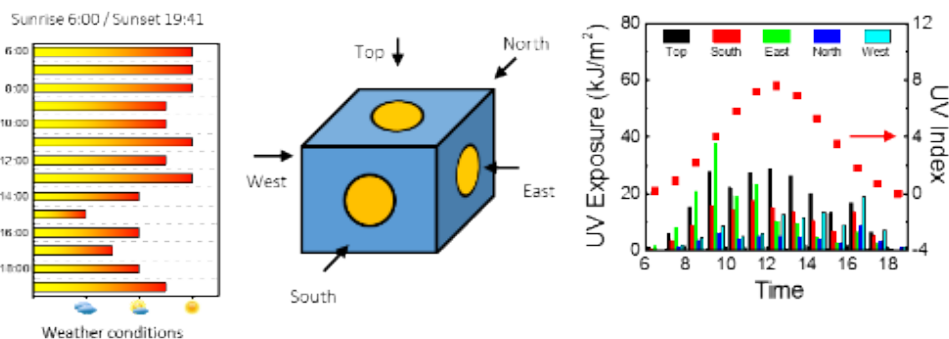


Figure 5: Outdoor UV dosimetry on different faces of a box. Left: weather conditions by time of day (qualitative); center: illustration of apparatus, with five patches on the faces of a cubic box placed outdoors for the duration of the day; right: UV exposure measured by five patches, hourly.

Development of the software for the mobile app, its user interface, and its

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supporting infrastructure.

The app of the proposed work will collect data from the sensor, combine it with user-configured data (skin type, age, sex, family history, mounting location, etc.) and local data (time, location, exposure duration, local weather, UV index, etc.) to present specific and actionable notifications on sun exposure levels and recommendations (exposure amount, sunburn risk level, sunscreen application, awareness, and prevention messages) for protection specific to the individual.

The app will be simple, intuitive, and easy to use. The specific goals for the development of the app are to produce a product with the following characteristics:

Intuitive, minimalist interface—a simple interface with simple instructions.

App development will include minimizing the effort required to learn the software, to upload data, and to access UV dose information.

Provision of specific data to inform the user of his/her UV exposure and sunburn risk levels and provision of specific recommendations for protection based upon the measurements. Feedback from users in exit interviews will help determine methods for providing timely advice that is relevant to users' stated or implicit behavior choices clearly, without irritating the users.

Data security, encryption, and information protection.

The unobtrusive dosimeter and the app will allow effortless real-time interaction with the participants' mobile phone. This advancement may promote behavioral change to a greater extent than has been possible in the past with daily text messages using GPS location to estimate UVL exposure.¹⁰

2.0 Inclusion and Exclusion Criteria:

Beta Testing to Evaluate System:

Six participants will be enrolled. Young adults will be recruited using IRB approved flyers. Each participant will be provided with a set of sensors and access to the corresponding mobile application on a phone provided to them during the testing and asked to provide feedback for one hour.

Inclusion/exclusion criteria for Beta testing young adults:

Inclusion: a) age 18-29 years old, b) familiarity with use of mobile apps on a smartphone, c) Non-Hispanic white or Hispanic with fair skin, d) history of one sunburn over the course of their lifetime.

Exclusion: unable to speak English

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Field test for feasibility and usability with structured interviews:

Screen for eligibility:

Ten young adults between the ages of 18-29 will be recruited for the field test. Recruitment for this phase will include the use of an IRB approved flyer posted around Northwestern University's Chicago and Evanston campuses. Once a participant reaches out to the Research Manager, an IRB approved recruitment script will be read or emailed to the participant. Each young adult will be consented using REDCap. After the young adult has consented, a sensor and an android phone will be sent to their provided address via FedEx, or the participant may obtain the sensors and phone in person at the Dermatology offices located at 645 N Michigan Ave. Each participant will be asked to use the sensor and transmit data five times each day for 14 days. At the conclusion of the 14 days, an in-person structured interview concerning acceptability and ease of use will be conducted. The study duration is expected to be 16 days, from baseline to exit interview.

Inclusion/exclusion criteria for young adults:

Inclusion: a) age 18-29 years old, b) familiarity with use of mobile apps and smartphones, c) have skin types 1-3, and d) willing to wear the sensor and able to transmit data for 14 days, which requires Wi-Fi in the home, and e) have a permanent address where study materials can be shipped.

Exclusion: unable to speak English

Lacking a secure Internet connection or very little experience with smartphones and mobile applications.

Unable to walk inside and outside independently

Vulnerable populations: No adults unable to consent, children, pregnant women, prisoners are eligible.

Prospective cohort study in a high-risk population of melanoma survivors aged 18-80.

Screen for eligibility:

Participants with a history of Stage 0 to IIB melanoma will be recruited by a research assistant (RA) in the surgical oncology clinics of Dr. Jeffrey Wayne and Dr. Karl Bilimoria and in the dermatology clinics. Participants will also be recruited using the Enterprise Data Warehouse (EDW) of Northwestern University to identify eligible subjects. When recruiting in the oncology and dermatology clinics, potential subjects will be approached by an RA as they are waiting for their appointment. The RA will inquire if they are interested in learning about a research study that is related to skin cancer prevention and will provide them with an IRB approved flyer to review. If interest is expressed by the potential subject, a detailed, IRB-approved recruitment script will be

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delivered by the RA. If the potential subject remains interested, the RA will proceed to provide a paper consent document to review. The consent process, of reviewing the consent in full and answering any questions, will occur in a consultation room of the surgical oncology clinics or consultation room of the dermatology clinic.

Melanoma Survivor Inclusion/exclusion criteria

Inclusion: a) history of Stage 0 to IIB melanoma, b) age 18-80 years old, c) willing to use the provided android smartphone, d) ability to walk inside and outside independently e) own a smartphone of their own, f) familiarity with the use of mobile apps, g) reliable wireless Internet connection to complete daily surveys, h) willing to wear the sensor for 21 days and transmit data and complete daily surveys i) willing to receive SMS text messages on their personal phone, j) complete an in-person exit interview after completing 21 days of data transmission.

In order to receive compensation for this study, the mobile phone and sensor must be returned before/on the day of the exit interview.

Exclusion: unable to speak English

Lacking a secure Internet connection or very little experience with smartphones and mobile applications.

Unable to walk inside and outside independently

Vulnerable populations: No adults unable to consent, children, pregnant women, prisoners are eligible.

3.0 Sample Size:

Enrolled

Beta test: 6

Field test for feasibility and usability with structured interviews = 10

Cohort study= 100

Total =116

We power our study using the primary outcomes of sun protection and UV exposure. Based on a simulation study using clustered longitudinal data, with 100 participants enrolled and an estimated 20% attrition yielding 80 evaluable participants after 21 days, we anticipate having adequate power to detect changes in sun protection and UVL data.

For sun protection, we power based on an effect size and for UV we assume a standard deviation of 0.3 SED/day.¹¹ We assume an intra-class correlation (ICC) of 0.5. Based on these assumptions we will have 80% power to detect differences between baseline and 21 days as small as .075 SED for UVL exposure and as small as 0.2 SD units for sun protection.

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4.0 Research Locations:

The study will be conducted at the Northwestern University Department of Dermatology clinical research offices. Recruitment and accrual procedures for melanoma survivors will occur in the surgical oncology offices of Dr. Jeffrey Wayne and Dr. Karl Bilimoria. Their offices are located on the 21st floor of the Northwestern Memorial Hospital Galter building, floor 21. The 16th floor of Arkes, which houses the dermatology clinics, will also be a site for recruitment and accrual.

5.0 Multiple sites:

NA

6.0 Reliance Agreements/Single IRB:

Northwestern University Institutional Review Board (IRB) will be the single IRB of record.

7.0 Procedures Involved:

Field test for feasibility and usability with structured interviews:

Study design of field test for feasibility and usability

This observational study will enroll 10 young adults in a 16 day field test of wearing the UV sensor and transmitting data.

Description of procedures and when performed

Participants will be recruited using IRB approved flyers that will be posted around the Northwestern Chicago and Evanston campuses. Interested participants that contact the Research Manager or RA's, by phone or email, will be read an IRB approved recruitment script. This script provides more detailed information about the study. If participant expresses interest and is eligible to participate, the consent document will be sent to their provided email address using REDCap. Once consented, a REDCap baseline survey will be emailed to participant. This baseline survey will collect contact information, demographics, and knowledge of sun protection and behaviors. Once the baseline survey is completed, the contact information containing the participants address will be used to send them the android phone with pre-installed mobile application, sun sensor, and written instructions on how to use the provided materials. If the participant prefers, all study related material can be picked up from the Dermatology research offices, located 645 N Michigan Ave. Suite 1050. For 14 days of the study, participants will be expected to wear the UV device and transmit data five times per day. Transmission times will be when the participant wakes up, 10 AM, 2 PM, 4 PM and before the participant

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takes off the sensor at bedtime.

On day 15 or 16, the participant will come to the Dermatology research offices, located at 645 N Michigan Ave, Suite 1050, for an exit interview about their experience wearing the sensor and using the corresponding mobile application. Compensation will be provided upon return of the mobile phone and sensor and completion of the exit interview.

The duration of the field test will be 16 days.

Prospective cohort study

Study design of the prospective cohort study

This prospective cohort design is a single group (Stage 0-2B melanoma survivors) X 3 (baseline, 10 and 21-day follow-up) over 21 summer days (June, July, and August). At day 10 of the study, remaining participants will be randomized 1:1 to receive goal attainment as either structured or unstructured options.

Description of procedures and when performed

The study will monitor compliance and user-satisfaction, and determine the efficacy of the program in enhancing sun protection in this high-risk population. Melanoma survivors will be recruited in the Dermatology clinics and in the Surgical oncology clinics of Dr. Jeffrey Wayne and Dr. Karl Bilimoria. The RA will give the sun protection study flyer to the melanoma survivor. If interested in participating, the RA will use an IRB approved script to explain the study in more detail. The RA will then consent the potential participant electronically using a tablet that contains the REDCap consent form. Consenting will be performed in a consultation room of the dermatology or surgical oncology offices. A baseline survey collecting contact information, demographics and sun protection knowledge will also be completed via REDCap. This survey should take about 10 minutes. Android phones and the sun sensor will be provided to each participant to transmit data. The RA will provide verbal and written detailed instructions on how to use the mobile application and how to transmit data from the sensor using the phone.

During the 21 days of the study (June, July, and August), melanoma survivors will be expected to wear the UV device while awake and transmit data five times each day. The transmission times are upon waking up in the morning, 10 AM, 2 PM, 4 PM and at bedtime. SMS text reminders will be sent to the participants' personal smartphone to transmit data. A daily sun protection survey will be sent to each participant on all active study days. This survey focuses on sun protective measure during outdoor activities that day.

At the mid-point of the study (about day 10), the sun protection survey will once again be sent via REDCap, half of the participants (chosen randomly) will receive an additional section of the survey that offers structured goal attainment options and the other half will receive unstructured goal attainment as a place

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for free text. . This randomly assigned survey will be again be administered, to the same randomly selected group, on the last day of the study. The final study visit will occur in person at the Dermatology research offices. The melanoma survivor will participate in a 20-minute exit interview to assess their compliance and satisfaction with the sun protection program, e.g. “What are your thoughts about whether you benefited from the sun protection program?” “Did the sensor make it easy/ difficult for you to keep up with sun protection?” “Was the frequency of the messages too little/ too much/ about right?” and “Do you have other thoughts, observations, or comments about the sun protection program?” The loaned phone will be returned at the final visit and the participant will be compensated with a gift card in the amount of \$200.

Data Analysis

1.1 Source records- not used

1.2 Data collected: cohort study

a) Demographic data, including skin type assessed by the user with a colorimetric scale will be obtained only at baseline.

b) Self-reported surveys. At baseline and 21 days, subjects will be complete the seven part survey used in our two prior RCTs. All our measures have evidence of being reliable (alphas .74 to .98). (Table 1)

Table 1. Self-Reported Measures			
Knowledge	Attitudes	Behavior [13-66]	
Recommended SPF number of sunscreen (α .89)	Importance: melanoma, having a tan, sun protection (α .89-.91)	Episode(s) sunburn or Skin irritation from sun (α .94)	
When to seek shade (α .92)	Concern about developing skin cancer (α .89)	Use sunscreen, protective clothing (α .85-.90)	
How to use sunscreen (α .92)	Recognize personal risk of melanoma (α .87)	Limit time outdoors before 10 AM, after 4 PM (α .93)	
Risk of developing melanoma (α .85)	Confident sun protection prevents melanoma (α .89),	Number of hours outdoors, weekday/ weekend (α .87)	
Melanoma can kill people (α .98)	Confident can perform sun	Seek shade (α .88)	Sensor reported UV dose every 2 hrs. from 10 AM and 4 PM

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	protection (α .93)		
Sun protection reduces risk (α .74)	Willing to change behavior (α .86-.94)	Deliberate tanning (α .97)	

To assess change in outcomes of seeking shade, wearing protective clothing, and using sunscreen from baseline to end of study, we plan on using mixed effects models with random slopes for each melanoma survivor (measuring total UV dose) and adjusting for UV protection.

c) Goal attainment. To assess change in outcomes of seeking shade, wearing protective clothing and using sunscreen the period prior to day 10 structured and unstructured goal attainment will be compared with the 11 days that follow goal attainment. We plan on using mixed effects models with random slopes for each melanoma survivor (measuring total UV dose) and adjusting for UV protection. As the behavior and correlation of these measures over time would be speculative, we provide power/effect size estimates for a paired t-test. With 50 melanoma survivors in each group, we have 80% power to detect a general effect size of 0.51. This would be an increase in sun protection of approximately 82 (assuming a standard deviation of 164)¹¹.

8.0 Incomplete Disclosure or Deception:

NA

9.0 Recruitment Methods:

Beta test: IRB approved flyers will be posted in approved areas of the Northwestern University campus.

Field test for feasibility and usability with structured interviews:

An IRB approved flyer will be posted in approved areas of the Northwestern University's Chicago and Evanston campuses.

Cohort study: In-person accrual and recruitment will occur in surgical oncology clinics of Dr. Jeffrey Wayne and Dr. Karl Bilimoria. The dermatology clinics of 16-Galter will also be a site of recruitment. The Enterprise Data Warehouse (EDW) of Northwestern University will be used to identify eligible subjects.

Recruitment methods:

Field test for feasibility and usability with structured interviews:

Potential participants, who contact the study team by phone or email after seeing an IRB approved campus flyers will be sent an IRB-approved email or receive an IRB approved scripted phone call explaining the research. The email and/or phone call will explain to each participant that they will be provided with a sun sensor and asked to use the sensor and transmit data for 14 days. In addition, the required in-person structured interview, post-14-days of wearing

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the sensor and transmitting data, will be explained to the participant. RAs will verify that patients meet the inclusion criteria. RAs will keep a password-protected log of all patients who contacted the study team, any related questions that were asked and, if necessary, declining participation or ineligibility.

Cohort study:

Melanoma survivors will be recruited in the Dermatology clinics and in the Surgical oncology clinics of Dr. Jeffrey Wayne and Dr. Karl Bilimoria. Participants will also be recruited using the Enterprise Data Warehouse (EDW) of Northwestern University to identify eligible subjects. When recruiting in the oncology and dermatology clinics, potential subjects will be approached by an RA as they are waiting for their appointment. The RA will inquire if they are interested in learning about a research study that is related to skin cancer prevention and will provide them with an IRB approved flyer to review. If interest is expressed by the potential subject, a detailed, IRB-approved recruitment script will be delivered by the RA.

Number of subjects

Enrolled:

Beta test: 6

Usability test with Structured interviews= 10

Cohort study= 100

Total =116

Screened

Usability and feasibility test with Structured interviews= 40

Cohort study= 300

Total =340

10.0 Consent Process:

Beta test: written consent at the start of the beta test

Field test for feasibility and usability with structured interviews:
Electronic consent, via REDCap.

Cohort Study: Paper consent will be obtained by the RA in the clinical space of Dr. Jeffrey Wayne and Dr. Karl Bilimoria. The Dermatology clinical offices, 16-Arkes, may also be a site for consenting. If consenting in a clinical setting, consent will be limited to consultation rooms to ensure good clinical practice. Research offices of June K. Robinson, located at 645 N Michigan Ave. Suite 1050, may also be a site of consent and study procedure instructions.

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Withdrawal of subjects

The circumstances under which subjects may be withdrawn from the research without their consent are that they are 1) lost to follow-up or 2) unable or unwilling to complete study procedures. Based on our previous longitudinal studies with this population, we anticipate that we will observe 20% attrition.

Participants will be contacted by the research team should they fail to complete an online assessment. Once due diligence is completed via three unanswered phone calls, texts, or e-mails, the participant will be considered terminated from the research.

11.0 Financial Compensation:

Beta Test: At the completion of beta testing, each participant will receive a \$60 gift card.

Usability test with structured interview: At the completion of the in-person structured interview, after 14 days of using the sensor and transmitting data, each participant will receive a \$25 gift card and a parking voucher, if needed.

Cohort study: At the baseline visit, each participant will receive a parking voucher. At the end of study visit (after 21 days), each participant will receive a \$200 gift card and a full validation parking voucher, if needed.

12.0 Audio/Video Recording

Audio recordings will be utilized for the purpose of data analysis during beta testing and interviews with subjects.

Subjects may opt out of the audio-recording portion of the study. Subjects will be required, at time of consent, to opt in or out of being recorded.

The researcher will not share these recordings with anyone outside of the immediate study team. The recordings will remain in locked file cabinets and on computers with restricted and password protected access.

13.0 Potential Benefits to Participants:

Subjects will be participating in an observational study that may enhance their awareness of their risk of sunburn and over exposure to UV. The potential exists for study to help the subject identify times when their UV dose is high and modify their behavior to reduce their risk of sunburns.

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14.0 Risks to Participants:

The potential risks to participants are expected to be minimal, if they occur. Subjects will be participating in an observational study that may enhance their awareness of their risk of sunburn and over exposure to UV. All study participants will be provided with an email address and phone number to contact study staff in the event they have concerns. The research assistant will communicate other concerns to the PI.

Because of the potential for participation in the study to help the subject identify times when the UV dose is high, we feel that the potential benefits, in reduced sunburns and UV dose, to the subject outweigh the risk of potential enhanced anxiety in discovering their UV dose. Should subjects report or exhibit high levels of anxiety a referral for psychological support will be made.

We do not believe that subjects in this study will be exposed to any risk of physical or psychological harm as a result of either the intervention or research processes. Our measures do not assess individuals at risk of immediately harming themselves (e.g. suicide); therefore we will not have to screen the data to potentially intervene with individuals who may be a risk to themselves.

There are no anticipated risks to others who are not participants.

15.0 Provisions to Protect the Privacy and Confidentiality of Participants and the Research Data:

This research includes provisions for protecting the privacy of participants. Study interactions will mainly take place online and via the phone. The research team will make every effort to address the questions and concerns of potential and current participants. Furthermore, the research team will ensure interactions with potential and current participants are not overheard. Steps will be taken to ensure that the participants feel at ease. To reduce the sense of intrusiveness a subject may experience in response to survey questions, subjects will be informed that they may decline to provide any information they do not wish to disclose. The information being collected is limited to only the minimum amount of data necessary to accomplish the research purposes. Participants will be assigned a unique subject number, and all study forms will only with this number. Any sensitive, identifiable participant information will be kept separate from study forms and securely stored in a password protected file on an encrypted server on the Northwestern network. The PI will be responsible for storing the list of subjects with the subject numbers in a locked cabinet in her research office and will not release this.

The research team will only be permitted to access study-related, subject-reported information.

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All study-related information will be included as data (surveys, interview notes, audio recordings, progress notes, etc.). Data will be coded when working on our own personal computers. Our systems are guarded against outside entry by Northwestern's own firewall supporting 128-bit encryption. This level of encryption provides the highest level of protection against hackers, computer break-ins, etc. No research assistants involved in coding or analyses will have access to the master list of participant names/ID numbers, but will maintain separate lists of names/email addresses, in order to initiate and track participation. Experienced research assistants will be employed and will receive training that includes emphasis upon the importance of confidentiality of information, and all personnel on the project will complete the required NIH training in the protection of human research participants. All staff will sign confidentiality statements at each site.

Data will be retained in separate locked file cabinets and on computers with restricted and password protected access, without links to the master code list. All data based on the research will be reported in aggregate form. No individual respondents will be identified. Electronic data will be maintained in a study specific database on the server of the Department of Dermatology at the Feinberg School of Medicine. De-identified data files will be uploaded and shared with Penn State via Northwestern Box. Paper-based files will be kept in a locked cabinet in a locked room within the Northwestern University Department of Dermatology research offices. Identifiable data will be kept separate from the case report forms and source documents. Data gathered as a result of this study are available to inspection on request by Food and Drug Administration or other government regulatory agency auditors, and the Northwestern University Institutional Review Board (IRB).

Only approved research personnel will have access to the stored data. The PI is ultimately responsible for receipt and transmission of the data. As per Department of Dermatology protocol, data will retained indefinitely after the completion of the study.

All data and other information in this study will be maintained confidentially. In order to protect against risks posed by a potential loss of confidentiality, we will take the following steps: First, subjects will be assured they are free to refrain from answering any questions they do not wish to answer. Secondly, all data will be identified only by a unique personal identifier (pin), which will be randomly generated for study purposes. Subjects will identified by a subject number. The Internet access to the study protects the identity of subjects by using a password. All data is recorded by a study number, which preserves the confidentiality of the information.

16.0 Data Monitoring Plan to Ensure the Safety of Participants:

NA

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17.0 Data, and if applicable, Specimen Banking:

NA

18.0 Data Sharing:

De-identified data files will be uploaded to Northwestern Box. The study statistician, Mary J. Kwasny, ScD, will use this data for analysis purposes.

Sharing of results with subjects

At the end of the study, summary data from the analysis will be provided to each participant in the cohort study. Each participant will be able to obtain their daily UV dose.

19.0 Qualifications to Conduct Research and Resources Available:

Dr. Robinson has been a board certified physician for over three decades and has conducted a NCI funded R01 and R21 of a similar nature. We will notify the Northwestern University IRB, our project officers, and NCI within 24-48 hours of any serious adverse event. We will provide an annual report to the small business summarizing all adverse events, should any arise.

All research assistants have CITI documents on file.

Other resources. Northwestern Medicine treats about 800 new melanoma patients/ year; therefore, there are adequate numbers of potential subjects.

Time: Both the PI and the research assistant are adequately supported by the SBIR to complete the research, once it is funded. Note this is a just-in-time application, and funding is assured. The PI will ensure that the RAs are thoroughly trained on the protocol, the research procedures, and respective duties and functions. The RAs will be readily available to participants for questions and technical troubleshooting. The PI and RAs will personally meet on a weekly basis to discuss study progress and review duties and functions as applicable. A continual, open dialogue among the PI, project manager of the small business, and RAs will be encouraged.

Facilities: The PI's office is located within the clinical research office of the Department of Dermatology of Northwestern University. Dr. Robinson's skin cancer control group occupies 500 sq. ft. with 3 offices and a small conference room. All standard office equipment is available for use including PC, fax, color printer, locked filing cabinets, etc.

UV measurement and sun protection

20.0 References:

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