Consent

Dr. Yelena Wu

RISE-UP Study

IRB_00157778

Version date: 10/27/2023

RISE-UP (Risk Information and Skin-cancer Education in Undergraduate Prevention) Study

Consent and Authorization Document

STUDY SUMMARY

You are being invited to take part in a research study because you are a student enrolled in undergraduate college classes. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Take time to decide whether or not to volunteer to take part in this research study.

The purpose of this study will be to provide undergraduate students information about skin cancer risk and prevention. The study will last about 15 months and will include 1 in-person visit, 1 virtual study visit and a series of 5 questionnaires. Some individuals will also be asked to wear a device that measures their exposure to ultraviolet radiation (UVR) and to answer brief daily questionnaires. Everyone in the study will be asked to answer survey questions including demographic information, existing knowledge of skin cancer risk factors and prevention measures, and current sun protection behaviors. Every participant will also receive education about skin cancer risk factors and prevention. We will follow-up with you by phone, text messages or e-mail in between the in-person study visit and the subsequent questionnaires.

You will be randomly assigned to one of eight groups that will receive a combination of either one, two or all three of the intervention components described below. The group you will be in is decided by chance, like flipping a coin. The components we are testing include:

Educational information about what causes skin cancer and how to prevent it. Providing a saliva sample to receive personalized skin cancer risk genetic testing results. A personalized printout of the participant's face in visible light and in UV light that shows existing skin damage. A one-page worksheet for creating a personalized action plan for using sun protection and avoiding tanning.

Please note: due to the randomization described above, it is likely that you will not receive the exact same intervention as classmates or friends who may also be participating in this study. In order to maintain study fidelity, we ask that you not discuss the specific intervention components and/or results you receive until after you have completed the study.

You may take this document home to read or to discuss with your family members or doctor before deciding to take part in this research study. Please take your time and read this information carefully. You should ask the research staff if you have any questions about this study, or if there is anything you do not understand. If you decide to take part in the study, you will be asked to sign this informed consent form.

STUDY BACKGROUND AND PURPOSE

The purpose of this study is to test several risk communication strategies to improve college students' engagement in skin cancer prevention behaviors, including sun protection behaviors (sunscreen, protective clothing, shade, peak UVR hours avoidance) and avoiding tanning behaviors (indoor, outdoor, unintentional).

Although skin cancer usually affects people later in life, it is becoming increasingly common in young adults. Ultraviolet radiation (UVR) exposure from the sun is the main risk factor for development of skin cancer, so efforts to reduce UVR exposure should start early in life. College students are at high risk for engaging in unintentional and intentional tanning behaviors that increase their UVR exposure. In general, they use inadequate sun protection strategies when they are outdoors.

STUDY PROCEDURES

First, you will meet with a study coordinator. You may ask as many questions as you like. If you decide to be in this research study, you will be asked to sign this form. There will be one study visit that will be conducted either in-person or remotely via Zoom. You will also be asked to complete a survey at 4 different time points during the study. The in-person/virtual visit will last a maximum of 90 minutes. We will also ask general information about you, such as age. You will be randomized to receive 1-4 of the risk communication strategies described below. You'll have an equal chance of being in each study group.

Education about skin cancer risks and prevention: Study staff will review information about risk factors for skin cancer, and general advice about skin cancer prevention behaviors. You will be provided with a written summary of this counseling. If you have questions about the information you receive, you will be encouraged to contact the study team. We will follow-up with you via phone calls, text messages or emails (whichever you prefer).

UV photo: Study staff will review information about risk factors for skin cancer, and general advice about skin cancer prevention behaviors. We will take your photo in ultraviolet light, and you will receive your personalized UVR photo that shows skin damage from the sun. You will be provided with a written summary of these results. If you have questions about the information you receive, you will be encouraged to contact the study team. We will follow-up with you via phone calls, text messages or emails (whichever you prefer).

Genetic testing: Study staff will review information about risk factors for skin cancer, and general advice about skin cancer prevention behaviors. You will provide a saliva sample that will be tested for MC1R gene variants that are known to be associated with an increased risk for developing skin cancer, and you will receive a summary of these genetic test results. You will be provided with a written summary of these results. If you have questions about the information you receive, you will be encouraged to contact the study team. We will follow-up with you via phone calls, text messages or emails (whichever you prefer). If you have additional concerns or questions about your genetic testing results, we will refer you to speak with a genetic counselor or to HCI's Family Cancer Assessment Clinic for further information and additional testing.

Action planning: Study staff will review information about risk factors for skin cancer, and general advice about skin cancer prevention behaviors. You will also receive guidance from a research assistant in completing a one-page worksheet for creating a personalized action plan for using sun protection and avoiding tanning. We will follow-up with you via phone calls, text messages or emails (whichever you prefer). If you have additional concerns or questions about your genetic testing results, we will refer you to speak with a genetic counselor or to HCI's Family Cancer Assessment Clinic for further information and additional testing.

Regardless of what group you are in, you will complete 5 questionnaires (baseline at the beginning of the study, intervention at the remote visit, one month following the remote visit, 4 months following the remote visit and 15 months following the remote visit.) These surveys can be done remotely, online or over the phone. We may contact you once more after this final survey to ask you questions verbally about your experience participating in the study.

You may be randomly selected to wear a UVR dosimeter sensor, which is a device that is worn on the wrist similar to a fitness tracking watch. This UVR sensor will collect data on your UVR exposure. The sensor would be worn during waking hours for 7 consecutive days. You would be asked to complete a daily check-in survey, and to return the device using a prepaid envelope at the end of the 7 days. You would receive additional compensation for this portion of the study.

RISKS

Although unlikely, it is possible that participation in this study could involve risks to you.

Risks of Answering Study Questions: There is minimal risk from answering the study questions. You do not have to answer any questions that you do not want to answer. You may stop answering questions at any time. All of your answers will remain confidential and will only be seen by the study team.

Risks of UVR Photo: You may be shown an image of your face taken with a UV camera. You might also be shown other skin damages caused by sun (e.g., sunburn, aging, mole excision scars). Some participants may be uncomfortable or concerned about indications of sun damage that may show up in the pictures.

Risks of Genetic Testing: If you do have a gene change that increases the chance of getting cancer, there are some risks from learning this. These include psychologic or emotional distress, loss of employment, or loss of insurance. Your family members could become upset to learn that they could be at increased risk, or that they may need increased screening or preventative surgeries. If at any point prior to, during, or after participation in this study, you want to talk about inherited risk factors that may increase you or your family members' risk of cancer and/or other diseases, we can refer you to a genetic counselor.

Unforeseen Risks: There may be risks from taking part in this study that are not known to the researchers right now. They may find out new risks while the study is going on. If this happens, the research staff will tell you the new information, whether it may affect you, and what, if anything, to expect. If you experience any psychologic distress prior to, during, or after participation in this study, we can refer you to the appropriate mental health provider.

BENEFITS

We cannot promise any benefits to others from your taking part in this research as we do not yet know if these communication strategies will improve your sun protection behaviors. However, if the study is successful, we may learn that these strategies significantly decrease UVR exposure and increase sun protection behaviors. Therefore, your participation can potentially benefit college students and other young adults in the future.

ALTERNATIVE PROCEDURES

You have the option not be part of this study. You can decide to stop at any time.

PERSON TO CONTACT

If you have questions, complaints or concerns about this study, you can contact Dr. Yelena Wu. If you think you may have been injured from being in this study, please call Dr. Wu at (801) 213-5653. Dr. Wu or one of her colleagues can be reached at this number between 8AM-5PM, Monday through Friday.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

VOLUNTARY PARTICIPATION

Participation in this research study is voluntary. You have the option to not be part of this study. Your decision to participate or not participate will not affect any other part of your care or studies at the University of Utah. Refusal to take part or stopping participation will not result in any penalty or loss of benefits to which you are entitled. Your decision to take part or not take part will not affect your legal rights, available remedies or the quality of health care that you will receive at this hospital.

RIGHT OF INVESTIGATOR TO WITHDRAW

We expect to continue the study until all participants have been enrolled and all of their information has been collected. However, the study may be stopped at any time by the researchers at this institution. The researcher may also withdraw you from the study without your approval. One reason this may happen is because the researcher feels it is necessary for your health and safety. Another reason is if the entire study is stopped.

COSTS AND COMPENSATION TO PARTICIPANTS

There will be no cost to you to take part in the research study. All study-related equipment and procedures will be provided at no cost to you or your insurance company.

As compensation for participation in the in-person study visit, you may be given a nominal amount of extra credit and/or a gift card after both study visits and additional questionnaires you complete with value increasing overtime, for the in-person visit: $15, for the second visit conducted virtually: $15, for the 1 month follow up assessment: $25, for the 4 month follow up assessment: $25, for the 15 month follow up assessment: $40. In total, you could earn up to $120. You will only be allowed to select one method of compensation at a time (i.e. if you choose to receive extra credit, you cannot receive the gift card compensation and vice versa). However, the form of compensation you select may change over time, e.g., if you select extra credit for your first two assessments, and then your class ends, then you may receive gift cards for the remaining assessments. You will be asked to select which compensation option you would like to receive in your first study questionnaire.

Participants who complete the UVR dosimeter monitoring will receive additional compensation. You will receive an additional $2 for completing each daily questionnaire, and $1 for completing all questionnaires for a total of $15. You will also receive $15 for returning the device. Altogether you may earn up to $30 for participation in the UVR monitoring portion of the study.

NUMBER OF PARTICIPANTS

We expect to enroll approximately 600 participants at the University of Utah.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow us, the researchers in this study, and others working with us to use some information about your health for this research study. This is the information we will use and disclose in our research records:

Demographic and identifying information like name, gender, age, race, level of schooling, address, telephone number, email address. We will also collect your UID to ensure participants are only enrolled in the study once. Related medical information; such as who in your family has been diagnosed with skin cancer. Sun safety habits and information collected from survey responses, (including biophysical information such as facial coding and/or eye tracking using iMotions during education presentations). Biospecimens: Saliva sample

How we will protect and share your information:

We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored in your research record but not in your medical record.

In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:

Members of the research team at University of Utah Members of the University of Utah U of U Health Research facilities team who will process saliva samples Members of the research team at Memorial Sloan Kettering Cancer Center The University of Utah Institutional Review Board (IRB), which reviews research involving people to make sure the study protects your rights Representatives from the National Institutes of Health (NIH) who is the funding source for this study

If we share your identifying information with groups outside of University of Utah Health, they may not be required to

follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form.

If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at University of Utah Health.

What if I decide to Not Participate after I sign the Consent and Authorization Form?

You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

SAMPLING FOR GENETIC TESTING

Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications and responses to treatment. Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease. The results of the study of your samples from this project will be used for research purposes only. Your saliva sample that is collected for this research study will not include whole genome or whole exome sequencing. This means that the researchers have no plans to look at or try to "read," the protein information that makes up your genes (DNA) from your sample

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information. This law generally offers the following protections:

Health insurance companies and employer-based group health plans may not request your genetic information that we get from this research. Health insurance companies and employer-based group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. All health insurance companies and group health plans must follow this law. All employers with 15 or more employees must follow this law as of November 21, 2009. The protections offered by GINA apply regardless of when the research that obtained the genetic information was conducted, even if prior to the effective date.

Be aware that this law does not protect you against discrimination on the basis of your genetic information by companies that sell life insurance, disability insurance, or long-term care insurance.

The information collected for this research study will be stored on secure servers at the University of Utah. The database has information from all of the participants. Your information in the database will only be used for statistical analysis and may appear in scientific publications but will not identify you. The saliva samples analyzed will include personal identifiers, and after the present study is completed the samples will be destroyed.

The use of your data and biospecimens may lead to new tests, drugs, devices, or other products or services with commercial value. These products or services could be patented and licensed. There are no plans to provide any payment to you should this occur.

CONSENT

_____

Please INITIAL the appropriate statement to indicate whether or not you give permission for future contact.

I give permission to be contacted in the future for research purposes.

YES _____ (Please initial)

Please INITIAL the appropriate statement to indicate whether or not you give permission for future contact.

I give permission to be contacted in the future for research purposes.

NO _____ (Please initial)

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep. I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

Participant's Name _____

Participant's Signature _____

Date _____

Name of Person Obtaining Authorization and Consent _____

Signature of Person Obtaining Authorization and Consent _____

Date _____