

ASSENT DOCUMENT

Who are we and what are we doing?

We are researchers from Huntsman Cancer Institute at the University of Utah. We invite you to take part in STARS because you are a student at a rural high school in Utah. It is your choice whether to participate.

The purpose of the study is to teach you about skin cancer prevention. The study will last around six months. Everyone in the study will be asked to answer questionnaires and receive information about skin cancer risks ways to lower their risk.

There are few risks to being in this project. You may become more aware of sun protection and skin cancer.

*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 you will **NOT** take part in the program, you will be asked to notify the research staff and/or school.*

Why are we asking you to be in this research study?

The purpose of this research study is to provide skin cancer prevention education in rural Utah schools. Melanoma is the deadliest form of skin cancer, and people in rural areas are at higher risk developing advanced skin cancer compared to those in urban areas. Our goal is to help children and teenagers in rural communities develop healthy skin cancer prevention habits from a young age.

Before you decide if you want to participate in this research project, it is important for you to understand what will be asked of you. Please read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you will take part in this project.

What happens in the research study?

We will provide a skin cancer education program to you and other students at the school. This program will include education on sun protection and skin cancer prevention. Additional parts of the program may include: 1) interactive activities help you plan to do skin cancer prevention behaviors, and 2) your face being photographed using a camera that shows skin damage from ultraviolet radiation (UVR) exposure.

You will be asked to complete a baseline questionnaire before the program, and two follow-up questionnaires: one short-term assessment one month after the program, and one longer-term assessment six months after the baseline. After the first intervention, you might be asked to provide some feedback on the program through a questionnaire and/or interview. Our study procedures include text messages, phone calls, and emails from the STARS study to study participants to send study questionnaires.



Will any part of the research study hurt you?

Although unlikely, it is possible that participation in this study could involve the following risks:

Possible UVR photo risks: Participants might be shown an image of their face taken with a UV camera. They might see skin damage caused by sun or other sources (e.g., sun burn, aging, mole excision scars). Some participants might be uncomfortable or concerned about the sun damage that might show up in the pictures.

Possible questionnaire risks: There is minimal risk associated with answering the study questions. Participants do not have to answer any questions that they do not want to answer. They may stop answering questions at any time without affecting their medical care. All of your answers will remain confidential.

Students who choose to participate in the study will be asked to complete activities (e.g. questionnaires, educational sessions) that take class time. Depending on the teacher's choice, the time spent completing study procedures might affect other class activities.

Even though we do everything we can to protect the identity and privacy of participants, there is still a risk that data could be traced back to an individual or family. Some data that have been distributed for approved research use cannot be retrieved.

Will the research study help you or anyone else?

We do not know for sure if being in this research study will help you.

What if you have any questions about the research study?

It is okay to ask questions. If you don't understand something, you can ask us. We want you to ask questions now and anytime you think of them. If you have questions, complaints or concerns about this study, you can contact Dr. Tammy Stump. If you think you may have been injured from being in this study, please call Dr. Stump at (801) 646-4201. Dr. Stump 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

Do you have to be in the research study?

You do not have to be in this study if you don't want to. Being in this study is up to you. No one will be upset if you don't want to do it. You can take your time to decide. You can talk to your parent or guardian before you decide. Even if you say yes now, you can change your mind later and tell us you want to stop. Your choice will not affect your grade in any way. If you choose to not participate, we will work with your school and teacher to provide an alternative for you.



Will it cost anything to be in the research study?

There will be no cost to you or your child 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.

Will I be compensating for being the research study?

Students who complete each questionnaire will receive a \$5 gift card after the completion of the assessment questionnaire.

Students will be entered into a drawing to receive a \$75 gift card for each questionnaire they complete. Each student who completes the questionnaires will have an equal chance of being selected to receive the gift card.

Students who complete a study feedback interview will receive \$25.

How many participants will be in the study?

We expect to enroll approximately 100 high-school students in Utah.

Who will see the information about you?

Participating in this study means you allow us, the researchers in this study, and others working with us to use some information about you for this research study.

This is the information we will use and include in our research records:

- Demographic and identifying information like name, diagnosis, gender, age, race, level of schooling, and information about relatives.
- Related medical information about you like who in the family has been diagnosed with melanoma or any form of cancer.

How we will protect and share your information:

- We will do everything we can to keep your information confidential 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
 - The University of Utah Institutional Review Board (IRB), which reviews research involving people to make sure the study protects your rights
- 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 later on?

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

ASSENT

I confirm that I have read this document and have had the opportunity to ask questions.

Student name:

