

FLARE (Family Lifestyles, Actions and Risk Education) Intervention

Adult Consent and Authorization Cover Letter AND Parental Permission Cover Letter

STUDY SUMMARY

We invite you and your child to take part in a research study because you have a personal history of melanoma and at least one child between ages 8-17. It is your choice whether to be in the study.

The purpose of the study is to test a program designed to help children and families do things that could prevent melanoma. The study will last about sixteen months. Everyone in the study will be asked to answer questionnaires and participate in remote study visits. In the study visits, you'll receive information about skin cancer risk factors and prevention strategies. We will follow-up with you by phone, text messages, or e-mail in between study visits.

There is a risk that you or your child may feel upset talking about melanoma. You may benefit from being in the study, but there is no guarantee of benefits. You might help others in the future by being 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 and your child decide to take part in the study, you will be asked to give your verbal consent, and your child their verbal assent.

STUDY BACKGROUND AND PURPOSE

You and your child are being asked to take part in a research study. 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. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you want to volunteer to take part in this study.

The purpose of this study is to test an intervention program (FLARE) that helps children and their families do things that could prevent melanoma, like getting fewer sunburns.

The lead investigator for this study is Dr. Yelena Wu (Department of Dermatology and the Huntsman Cancer Institute, University of Utah). Other investigators from the University of Utah are also involved.

STUDY PROCEDURES

You and your child will be asked to participate in three study visits. These will be conducted remotely via videoconference with study staff. You will receive a mailed package containing study materials prior to the first study visit. The visits will be 2 weeks apart. Each visit will last



about 30 minutes. You and your child will be asked to complete questionnaires at the following times:

- 4 days prior to your study visits
- 4 weeks, 8 weeks, and 1 year after your study visits

These questionnaires will take about 30-40 minutes to complete.

Parents will receive an additional one-question assessment via text or email once monthly at the following times:

- Between the 8 week and the one year post-baseline assessment
- In the summer months after the one year post-baseline assessment

This study has two intervention groups. You will be randomized to either the FLARE intervention group or the standard education group. This means you will be randomly assigned to a group based on chance, like a flip of a coin. Neither you nor the researcher chooses your assigned group. You will have an equal chance of being in either group. Both groups will provide education about melanoma risk and may improve your family's sun protection behaviors.

You and your child will be asked questions on topics such as sun protection behaviors, sunburn occurrence, perceived melanoma risk, problem-solving skills, and demographic characteristics (e.g., sex/gender, race and ethnicity, age).

You and your child will also be asked to identify the child's skin tone using color charts. These color charts will be mailed to you at the start of the study. If you and your child do not complete the questionnaires on time, you will receive reminders via call, text or email to complete them.

We request your permission to examine records maintained by the Utah Cancer Registry or a Huntsman Cancer Institute affiliate site related to your cancer diagnosis. These records may include information such as type of cancer, time of diagnosis, and kind of treatment.

RISKS

The risks of this study are minimal. You or your child may feel mild distress when talking about your family's history of melanoma. You may also feel mild distress when focusing on the burden of practicing melanoma preventive behaviors. You should only participate in this study to the extent that you feel comfortable. If you feel upset from this experience, you can tell the research team. They will tell you about resources available to help.

BENEFITS

There are no direct benefits for taking part in this study. However, you may learn new skills to help you practice melanoma preventive behaviors. You will also help to create a new program that could help other families in the future.

ALTERNATIVE PROCEDURES

You and your child 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) 213-6291. 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 and your child 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 and your child 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 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.

You and your child will receive separate gift cards for each questionnaire totaling up to \$90 each.

NUMBER OF PARTICIPANTS

We expect to enroll approximately 750 participants at the University of Utah and affiliated sites.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Giving your verbal consent to 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 include in our research records:

- Demographic and identifying information like name, date and location of birth, gender, age, race, level of schooling, information about relatives, address, residential history, type of employment, telephone number(s), and e-mail address
- Cancer information: records from the Utah Cancer Registry or a Huntsman Cancer Institute affiliate site related to cancer diagnosis
- 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 you and your child's information private. However, we cannot guarantee this. Study information will be kept in a secured manner. 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 you or your child's 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 you or your child's 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 give consent and parental permission?

You can tell us anytime that you do not want you or your child to be in this study and do not want us to use your or your child's 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 or your child and you both 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.

CONSENT

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

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.

The research team may contact me about future research and relevant clinical trials that may be of interest or for other matters related to this study.

PARENTAL PERMISSION

I confirm I have read the information in this parental permission form and have had the opportunity to ask questions. I voluntarily agree to allow my child to take part in this study. We may contact you and your child about future research and relevant clinical trials that may be of interest to you or your child, or for other matters related to this study.

By answering our questions, you are giving your consent to be in this study and your permission for your child to participate in this study, and to be contacted by our research team.

We greatly appreciate you participating in our study.



FLARE (Family Lifestyles, Actions and Risk Education) Intervention

Assent Cover Letter to Participate in a Research study

WHO ARE WE AND WHAT ARE WE DOING

We are from the University of Utah and Huntsman Cancer Institute. We would like to ask you to be in a research study. A research study is a way to find out new information about something. We are doing a research study to learn how to help people your age and their families do things like wearing sunscreen.

WHY ARE WE ASKING YOU TO BE IN THIS RESEARCH STUDY?

We are asking you to be in this research study because you have a family history of melanoma, a type of skin cancer. We want to help families do things that could prevent melanoma.

WHAT HAPPENS IN THE RESEARCH STUDY?

If you decide to be in this research study and your parent or guardian agrees, this is what will happen:

- You and your parent will be randomly (like flipping a coin) assigned to one of two groups. Both these groups will help teach you about risks of too much sun.
 - 1) FLARE Intervention Group
 - 2) Standard Education Group
- Your family will be asked to have 3 study visits with us using a computer. During study visits, someone from our team will talk with you and your parent about ways to protect your skin from the sun.
- You will be asked to complete questionnaires, 6 times. This will be at:
 - o 4 days before each of the visits
 - o 4 weeks after the end of the visits
 - o 8 weeks after the end the visits
 - o 1 year after the end of the visits
- You will also be asked to identify your skin tone using color charts that will be mailed to you.

WILL ANY PART OF THE RESEARCH STUDY HURT YOU?

We don't expect that any part of the study will hurt you. If you feel uncomfortable, sad, or worried during the study, please tell us. We will try to make you feel better if this happens. You can stop at any time if you want to.

WILL THE RESEARCH STUDY HELP YOU OR ANYONE ELSE?

This study could help you and your family do things that help prevent melanoma. It may make you more aware of things you can do to protect your skin from the sun.

WHO WILL SEE THE INFORMATION ABOUT YOU?

Only the researchers or others who are doing their jobs will be able to see the information about you from this research study.

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 a question later that you didn't think of now, you can call Dr. Yelena Wu at (801) 213-6291 or ask us the next time we see you.

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. Even if you say yes now, you can change your mind later and tell us you want to stop.

You can take your time to decide. You can talk to your parent, guardian, or legally authorized representative before you decide.

We will also ask your parent, guardian or legally authorized representative to give their permission for you to be in this study. But even if that person says "yes" you can still decide not to be in the research study. Your doctors will continue to take care of you even if you decide not to be in this research study.

AGREEING TO BE IN THE STUDY

I was able to ask questions about this study. Agreeing to this form means I am giving my assent to participate in this study. We might contact you and your parents in the future to see if you're interested in other studies like this one, or about other things related to this study. We really appreciate you participating in our study.

By answering our questions, you are agreeing to participate in this study.