

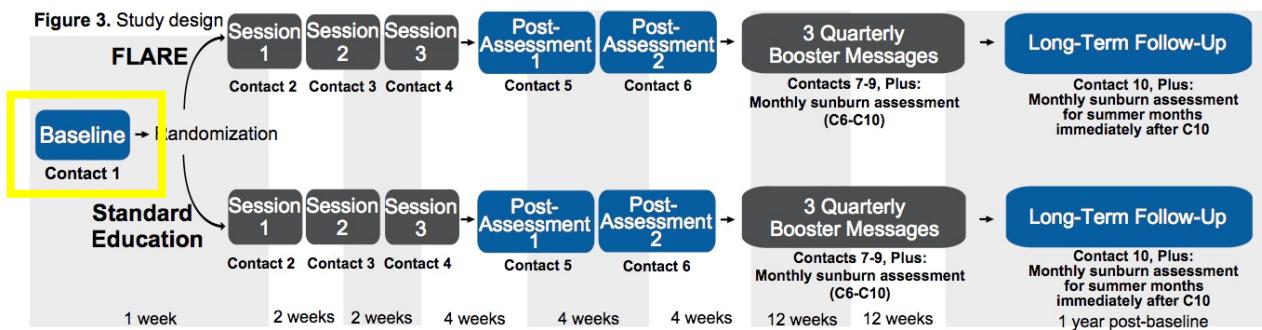
**The FLARE Skin Cancer Prevention Intervention for Children of Melanoma
Survivors**

NCT04201223

October 12th, 2023

Consent (Contact 1): Consent/Accent (by Phone) – Research Assistant

(Note from Sam: Best to make a copy of this document for each participant, so that you can write their info down! Also, heads up, make sure to check availability for those who could conduct a pre-session beforehand ☺)



Goals of Consent (Contact 1)

- Establish rapport with family
- Consenting parent participant
- Assenting child participant
- Inform dyads of study next steps

Reminder text day before:

“Hi [name], this is a reminder about your consent call with the FLARE study team tomorrow at [TIME]. Please have the two documents we emailed you pulled up and have your child who is participating with you present. If you did not receive an email with these documents, let me know and we can resend them. Let me know if this time no longer works for you. Thank you!”

Consent/assent contacts are done by the Research Assistant.

If consent call does not answer, leave the following message (KEEP MESSAGE HISTORY OPEN IN GOOGLE VOICE, DO NOT ARCHIVE): Hi [parent name]! This is [RA name] from the FLARE study at the Huntsman Cancer Institute. I am calling to go over the consent documents I sent to you last week, but I'm sorry to have missed you! Please give me a call back at (801) 213-6291 and we can schedule another time. Thank you!

Send the following text or email (depending on participant preference) if no call back/response within 3 days: Hi [parent name]! This is [RA name] from the FLARE study at Huntsman Cancer Institute. I'm sorry we missed each other for our call to go over the consent documents! Do you have time this week or next to reschedule that consent call?

START OF CONSENT CALL:

1. Ensure parent and child are both present for the consent call.

"Hi, is this [parent name]? This is [RA name] calling from the FLARE study at the Huntsman Cancer Institute. I'm calling to go over the consent documents I sent to you and [child name] last week. Is now still a good time for you to go over these documents?"

Great! Today I'll be reviewing with you the documents that I sent over as a part of that email last week, and then at the end I'll tell you about the next steps of the study. Are you able to pull up those documents in front of you now, on your phone or computer or email?

[wait for the participant to have the documents pulled up]

Okay, you should see two documents in that email I sent to you. The consent and parental permission form is for you, [parent], and the assent form is for [child name]. Is [child name] there with you to review the documents with us?

[wait for parent to confirm that child is on the phone listening as well]

[address child] *Hi, [child name]! My name is [RA name] and I'm a research assistant with the FLARE study at the Huntsman Cancer Institute. How are you doing today? [wait for response] Great! I'm going to talk with you and your parent today about a research study we're doing at the Huntsman Cancer Institute, and if you have any questions you can ask me at anytime, okay?*

2. Establish Rapport with Families (especially the children)

At the beginning of each contact or between study procedures, ask the families/children about themselves (e.g., what grade they're in, what they like to do at home or for fun, etc.). Jot some notes down on their answers at the end of the session so that you can build on this rapport and the details at future sessions.

This does not have to be too extensive, just one or two general questions is helpful in making this a positive experience for the family.

- How is school going?
- How is your family surviving this crazy weather?

3. Explain Agenda for today

"Thank you both for taking the time to speak with me! Today, we will go over consent forms for the study. These forms will give you more information about the research study and any risks. We will go section-by-section for each form – the consent form is for parents and the assent form is for children. Feel free to ask questions at any time."

4. Gift Card Schedule

"The first document I want to go over with you is the Gift card schedule. Will you let me know when you are looking at this? [pause] This shows how compensation is spread out over the next year and a half. You will receive three amazon e-gift cards over the course of the study. Your compensation depends on the number of surveys you complete, and each one is worth \$5. Do you have any questions about this?"

5. Parent Consent

"Let's move on to the consent form with you, [parent's name]. Are you looking at the consent form? It is titled "FLARE Consent and Parental Permission" in the email.

[wait to confirm the parent is looking at the consent form]

I'll now summarize the sections on this form, and please feel free to ask questions at anytime.

➤ Study Summary

"This section summarizes the study and describes the purpose of the study, what the study involves, and possible risks. The purpose of this study is to test programs designed to help children and families do things that could prevent melanoma. The study lasts 16 months, and everyone will be asked to answer questionnaires and participate in remote study visits."

➤ Study Background and Purpose

"This section explains why we are running this study. We are looking for new ways to help children and their families decrease their risk for developing melanoma."

➤ Study Procedures

"This section describes the study sessions, and the questionnaires we will ask you to complete. We will ask you and your child to participate in 3 intervention sessions with a member of our team. These sessions will be done via videoconference. Each session will be 2 weeks apart, and will last approximately 30 minutes. We will mail all study materials before your first study session."

You and your child will be asked to fill out online questionnaires about 4 days before your final intervention session, and 4 weeks, 8 weeks, and one year after these intervention sessions. These questionnaires should take 15-30 minutes to complete. We will also be sending you a brief assessment via text or email once monthly between the 8 week and one year assessment, as well as in the summer months after the one year assessment."

You and your child will both be randomly assigned (like a flip of a coin) to receive one of two intervention groups. Neither you nor the researcher chooses your assigned group. Regardless of which group you're assigned to, the number of sessions and assessments is the same. Both groups receive information about melanoma risk and prevention.

For the questionnaires, you and your child will be asked questions, such as about your sun protection behaviors, sunburns you may experience, and information about yourself and your child such as your gender. We will ask you and [child's name] to identify [child's name] skin tone using a skin tone color palette, which will be mailed to you at the beginning of the study. If you and your child do not complete these questionnaires on time, you will receive reminders from our team. Each questionnaire link will expire two weeks after being sent to you.

Additionally, you as the parent may be randomly selected to participate in a post-intervention interview over zoom or phone call. This would take place around one month after your video sessions, should be no longer than 30 minutes in length, and would ask about your experience in the study and what tools you gained from the intervention.

We also request your permission to examine records maintained by the Utah Cancer Registry or an HCI-affiliated site related to your cancer diagnosis. These records may include information such as type of cancer, time of diagnosis, and kind of treatment."

➤ Risks

"This next section outlines the potential risks associated with participating in this study. It's possible that you or your child may feel mild distress when talking about your family's history of melanoma or when focusing on the burden of practicing melanoma preventive behaviors. Please know that you should only participate in study procedures to the extent that you feel comfortable. If you feel upset from this experience, please tell the research team, who will inform you of resources available to help."

➤ Benefits

"Although we cannot promise any direct benefits to you for participating, you may learn new skills to help you practice melanoma preventive behaviors. Through your participation, we may gain insight into successful strategies to help families at risk for melanoma in the future."

➤ Alternative Procedures

“Please know that you have the option to not be a part of this study and you can decide to stop at any time.”

➤ Person to Contact

“This section includes contact information for the institutional review board and research participant advocate.”

➤ Voluntary Participation

“As I mentioned before, participation in this study is voluntary. If at any time you no longer want to participate please let us know. Your decision to participate or not participate will not affect any other part of your care or studies at the University of Utah.”

➤ Right of Investigator to Withdraw

“This section is stating that we have a right to stop this study at any time, if necessary for your health and safety.”

➤ Costs and Compensation to Participants

“There are no costs to you and your child for participating. You and your child will receive gift cards for each completed assessment, totaling up to \$90 each. These gift cards will be sent to you a few times throughout the course of the study. Your first gift card will arrive approximately 8 weeks after your last video session with the team.”

If you are randomly selected for the interview, you as the parent would receive an additional \$25 in compensation.

➤ Number of Participants

“We expect to enroll approximately 750 people.”

➤ Authorization for Use of Your Protected Health Information

“By giving your verbal consent today, you allow us, the research staff, to use some information about your health. This information is discussed further in this section, as well as how we will protect this information.”

➤ What if I decide to not participate...

“Again, if at any time you want to withdraw from the study, you may do this, even after you give your verbal consent.”

➤ Consent

“Do you have any questions about what I just went over?”

[Answer Any Questions]

“Now I’ll ask you to take a look on the form at the section near the bottom of the fourth page called “consent” – are you looking at that section?

“Now I’ll ask you to take as much time as you need to please read the three statements that follow that title “Consent”, and then when you’ve had enough time, please verbally indicate to me whether or not you agree to take part in this research study and disclose health information for purposes related to this study.”

[Wait to proceed until participant verbally agrees]

“So by participating in this study, meaning filling out study questionnaires or attending the online study sessions, you understand that you are consenting to participate?”

[Wait to proceed until indicates they understand]

➤ Parental Permission

“On this same page you will see a section for parental permission. Please read the statement about allowing your child to take part in this study. Please verbally indicate whether or not you agree with this statement and allow your child to take part in this study.”

“Thank you! We hope that you’ll find participating in this study to be a good experience.”

6. Child Assent

“I am now going to go over and summarize each section of the assent form for [child’s name]. [Child’s name], are you looking at the form titled “FLARE Assent” in the email?

Great! I’ll summarize these sections with you now, and if at any time you have any questions [child’s name], feel free to ask me, okay?”

➤ Who are we and what are we doing

“This section talks about who we are and where we are from. We are researchers from the University of Utah, and we would like to ask you to be in a research study. We want 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 your family has a history of melanoma, a kind of skin cancer. We want to learn how we can help families prevent melanoma."

➤ What happens in the research study

"If you agree to participate in this study, you and your parent will be randomly assigned to receive one of two educational programs. "Randomly assigned" is similar to flipping a coin – you will have an equal chance of being in either group. Both of these groups will teach you about risks of too much sun."

You and your parent will have 3 study sessions with us, and these will be done online. We will talk with you about ways to protect your skin from the sun. We will also ask you to complete questionnaires before and after your last study session. We will ask you things like how you protect your skin from the sun and if you get any sunburns. You will also be asked to identify your skin tone using a color palette we will mail to you."

➤ Will any part of the research study hurt you?

"No part of this study should hurt you. If you feel uncomfortable, sad, or worried talking about certain things or answering certain questions, please let us know and we will try and make you feel better. You can stop this research study at any time."

➤ Will the research study help you or anyone else?

"This study may help you and your family do things that can help prevent melanoma."

➤ 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?

"If you have any questions about the research study, or if you don't understand something, you can ask us. Feel free to ask us questions any time you think of them. Here are some different ways you can ask us questions."

➤ Do you have to be in the research study?

"You do not have to be in this research study if you don't want to. No one will be upset if you don't want to do it. Even if you say yes now, you can always change your mind later. We also asked your parent or guardian to give their permission for you to be in this research study, but even if they said yes, you can still decide

not to be in the study. Your doctors will continue to take care of you even if you decide not to participate. You can take your time to decide.”

- Agreeing to be in the study (Assent)

“Do you have any questions about what I just talked about?”

[Answer Any Questions]

“Okay, just like I asked your PARENT to do, I’ll have you now look at the bottom of the second page to the section titled “Agreeing to be in the study” – do you see that section?

“Great, now I’ll ask you to take as much time as you need to read the following statement below with your parent or guardian. When you’ve had enough time and finished up, please verbally indicate whether or not you agree to take part in this research study.”

[Wait to proceed until participant verbally agrees]

“So by participating in this study, meaning answering study questionnaires or attending the online study sessions, you understand that you are agreeing to participate?”

[Wait to proceed until indicates they understand]

7. Explain next steps of study

“Great! Thank you both for your attention during that consent portion and for your willingness to participate in the FLARE study.

“In the next couple of days, I will be sending you the first set of questionnaires we’ll ask you to fill out, one for [parent] and one for [child]. After you complete the questionnaires, we mail you a package containing the skin tone palette and other study materials. Note that on the first questionnaire, you will be asked to identify [child]’s skin tone. For this first questionnaire, you’ll use the palette on the screen. For subsequent questionnaires, you’ll use the palette we mail to you with the study materials. Does that make sense?

We can also mail you a webcam if needed. Do you currently have a device with a webcam such as a computer, iPad, or cell phone that you can use for the sessions with a member of our study team?”

[If NO, inform them that they can be provided with a webcam for the duration of the study.]

“Also, do you have internet access in your home that you can use for the sessions as well?”

[If NO, troubleshoot with dyads to figure out a way to access internet, based on dyad needs and preferences.]

- 1) Assist in selecting a mobile device with broadband internet access to purchase;
OR
- 2) Provide dyad with a mobile device that has the necessary internet connectivity for the duration of their study participation; OR
- 3) Assist in identifying community locations (e.g. public library) where they can participate in the study using publicly available internet connections and computers.

8. Schedule Pre-Session 1 (Introduction and Testing of Zoom)

“After we send you these materials, we would like to walk you through downloading and testing Zoom, the software system we will use for the online intervention sessions, and logging into Canvas, the website where you’ll be able to review some materials to prepare for the online sessions. Ideally, we’d like to schedule this phone call in a couple weeks. We expect the call should take about 15 minutes. Two weeks from today is [day of the week], [date]. Would you prefer a [broad time, like morning] or a [broad time, like afternoon]? Great, would you prefer a [time, like 11AM] or a [time, like 12PM]? ”

[schedule the pre-session for no less than 2 weeks after the consent call, ideally a couple days more to allow adequate time to complete the questionnaires and mail the FLARE binder]

Date: [Click or tap here to enter text.](#)

Time: [Click or tap here to enter text.](#)

“That sounds great! We’ll call you on [confirm date] at [confirm time] to test Zoom and Canvas together. Does that sound OK?”

“Great! We hope that you’ll find participating in the FLARE study to be a good experience. If, for any reason, you end up not participating in some of the Zoom sessions, we will still get in touch with you to collect some information from you about your melanoma prevention habits. Your answers will help us find out whether the FLARE sessions are helpful to families’ melanoma prevention habits.”

“Does that all sound OK? Great. We will be in touch. Enjoy the rest of your day!”

After consent call is finished, reference the document on Box entitled “After Screen or Consent.docx” for instructions on what to do next!