**Protocol Title:** PREVENTATIVE SKIN CARE FOR CHILDREN UNDERGOING TARGETED THERAPY FOR CNS AND PNS TUMORS

**DF/HCC Principal Research Doctor / Institution:**
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**Main Consent**
**Version 16JUN2021**

If you are a parent or guardian of a child under 18 years old, the word "you" refers to your child. You, the parent, will be asked to read and sign this document to give permission for your child to participate.

## INTRODUCTION AND KEY INFORMATION

All research is voluntary. It is your choice whether you take part in this research or not. If you decide to participate, please sign and date at the end of this form. We will give you a copy and you can refer to this consent form at any time.

The following is a short summary of this research study to help you decide whether you would like to be a part of this study. More detailed information is provided later in this form.

For purposes of this research, you will be referred to as a "participant."

### 1. Why am I being invited to take part in a research study?

You are invited to take part in in this research study, because you have been diagnosed with a nervous system tumor and you will be receiving anti-cancer therapy with a MEK, Pan-RAF, or BRAF inhibitor.

### 2. Why is this research being done?

This research study will help us learn more about preventing skin changes that may occur in children who are getting treatment for nervous system tumors. We are interested in knowing whether gentle skin care, nail care, sun protection and dilute bleach baths might decrease the chances or the severity of skin changes





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that occur during treatment for nervous system tumors. This information may help us treat nervous system tumor patients in the future.

### 3. Who is supporting this research?

Boston Children's Hospital is supporting this research study.

Preventative skin care regimen materials including bleach, sunscreen, soap, lotion and emollients will be provided by the Dermatology Research Fund at the Jimmy Fund Clinic.

### 4. What does this research study involve and how long will it last?

**Before the research starts:**

The research study procedures include screening for eligibility and study treatment including evaluations and follow up visits.

You will receive a study treatment regimen that involves a preventative skin care routine along with regular dilute bleach baths. You will be followed for twelve weeks.

It is expected that about 8 people will take part in this research study.

Information about you and your health is personal and private. Generally it cannot be obtained without your written permission. By signing this form, you are providing that permission and your information may be obtained and used in accordance with this informed consent and as required or allowed by law. This means that researchers may obtain information regarding your past medical history, as well as specimens and samples from previous health care providers such as hospitals and labs.

### 5. What are the risks to participating in this study?

There are risks to taking part in any research study. The following are the risks associated with this particular study.

- You will have complete skin examinations at the initiation of your treatment, at six weeks after the start of your treatment, and at twelve

weeks after the start of your treatment, which may give you physical or emotional discomfort.
- You may be instructed to use sunscreen and/or lotions that you have not used before that may cause skin reactions.
- You may be instructed to undergo regular, dilute bleach baths at home that may cause skin reactions.
- You may feel uncomfortable about answering certain questions about your health.
- We may find something on your skin that requires follow up or skin biopsy.
- You may experience skin reactions to your cancer treatment despite skin care routines used during the study period.

## 6. Will being in this study benefit me in any way?

Taking part in this research study may or may not benefit you. We hope the information learned from this research study will provide more information about preventing skin changes that occur in children with brain tumors.

## 7. What are my options?

Taking part in this research study is voluntary. Instead of being in this research study, you have the following options:

- Decide not to participate in this research study

You have the right to choose not to sign this form. If you decide not to sign this form, you cannot participate in this research study.

You can stop being in the research study at any time. Leaving the research study will not affect your medical care. You can still get your medical care from your hospital or Investigator.

If you choose to not participate, or if you are not eligible to participate, or if you withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

## A. WHY IS THIS RESEARCH STUDY BEING DONE?

Some chemotherapy agents such as MEK, BRAF and pan-RAF inhibitors can cause skin problems as a side effect. The can include problems such as sunburn and rashes. This research study will help us learn more about preventing these skin changes that may occur in children who are getting treatment for nervous system tumors. We are interested in knowing whether gentle skin care, nail care, sun protection and dilute bleach baths might decrease the chances or the severity of skin changes that occur during treatment for nervous system tumors. This information may help us treat nervous system tumor patients in the future.

## B. WHAT IS INVOLVED IN THE RESEARCH STUDY?

You will be asked to perform a preventative skin care routine that includes daily sun protection, daily gentle skin care, nail care and every-other-day dilute bleach baths for the duration of the study

**Before the research starts (screening):**
Before participating in this research study, we will ask you some questions to find out if you can be in the research study. Your clinic and hospital records will also be reviewed.

If these tests show that you are eligible to participate in the research study, you will be eligible to participate in the research study. If you do not meet the eligibility criteria, you will not be able to participate in this research study.

**After the screening procedures confirm that you are eligible to participate in the research study:**

Skin exams will be performed at three different times. The first exam will take place at the beginning of your treatment, the second exam will take place at six weeks after start of your treatment and the third exam will take place at twelve weeks after the start of your treatment.

At your visits:

- You will have a complete examination of your skin, hair, and nails.
- Photographs will be taken of your skin, hair, and nails.

- If you are under 12 years of age, you and your legal guardian will complete written surveys about any skin changes you have experienced since starting treatment. If you are 12 years of age or older, you can complete these surveys by yourself.
- The visit will take 30 minutes to 1 hour of your time.

You will receive counseling about gentle skin care, nail care and sun protection. You will be asked to:

1. Take short warm, not hot, showers or baths.
2. Use one of several recommended moisturizers immediately after bathing.
3. Wear mineral based sunscreen of SPF 30 or higher on a daily basis on all sun exposed areas.
4. Wear sun protective clothing when outdoors.
5. Limit sun exposure during peak hours of 10am-4pm.
6. Take warm 10-15 minute dilute bleach baths every other day
7. Trim your fingernails once a week and your toenails once a month after bathing

During the study, information will also be obtained from your clinic and hospital records including blood tests, physical exam findings, past and current medications, past and current medical history, biopsy results, and hospitalizations.

**Research Study Plan:**

| | Baseline | 6 weeks | 12 weeks |
|---|---|---|---|
| History | X | X | X |
| Physical exam | X | X | X |
| Written surveys | X | X | X |
| Dry skin care, nail care, sun protection, and dilute bleach bath counseling | X | | |

If you are enrolled in this study, you will be in this research study during the course of your treatment. At the initial visit when you start treatment, at six weeks

after the start of your treatment, and at twelve weeks after the start of your treatment, you will receive a full skin examination and be asked to complete surveys about any skin changes you have experienced during this time.

**Planned Follow-up:**
We would like to keep track of your medical condition. Keeping in touch with you and checking your condition helps us look at the long-term effects of the research study.

In addition, you can stop participating in the research study at any time, however, the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

## C. WHAT ARE THE RISKS OR DISCOMFORTS OF THE RESEARCH STUDY?

There are risks to taking part in any research study. The following are the risks associated with this particular study.

- You will have complete skin examinations at the initiation of your treatment, at six weeks after the start of your treatment, and at twelve weeks after the start of your treatment, which may give you physical or emotional discomfort.
- You may be instructed to use sunscreen and/or lotions that you have not used before that may cause skin reactions.
- You may be instructed to undergo regular, dilute bleach baths at home that may cause skin reactions.
- You may feel uncomfortable about answering certain questions about your health.
- We may find something on your skin that requires follow up or skin biopsy.
- You may experience skin reactions to your cancer treatment despite skin care routines used during the study period.
- In a research study, all of the risks or side effects may not be known before you start the study.

At your visit, you will be given an opportunity to discuss any concerns you have about the study. We will do our best to minimize your discomfort or inconvenience. If at any time, this study becomes too burdensome, you have the right to discontinue participation in this study.

During the research study, you will be provided with any new information that may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

If we find something concerning on your skin, we will recommend appropriate care, which may include a follow up appointment or skin biopsy. If you are being evaluated during your oncology visit, rather than a dermatology visit, you will be scheduled for a formal dermatology visit in order to provide you with appropriate dermatologic care.

If you experience any adverse reactions to the skin care routines utilized in this study, including sunscreens, lotions, creams or dilute bleach baths, you will be instructed to discontinue them.

## D. WHAT WILL HAPPEN IF I AM REMOVED FROM THE STUDY OR DECIDE TO END MY PARTICIPATION IN THE RESEARCH?

You may be taken off the research study for any reason including:

- It is considered to be in your best interest
- The study treatment or procedures are found to be unsafe or ineffective
- There is any problem with following study treatments and procedures
- Your condition worsens
- A decision is made to end the study
- Or for other unforeseen reasons that make it necessary to stop your participation in the research study

You can also choose to stop participating in the research study at any time. Tell the research doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop. Leaving the research study will not affect your medical care outside of the research study.

If you decide to withdraw from a study that involves de-identified data it will not be possible to remove the data that have already been submitted to a database.

## E. WILL I BE PAID TO TAKE PART IN THIS RESEARCH STUDY?

You will not be paid for participating in this study.

## F. WHAT ARE YOUR COSTS?

Taking part in this research study will not lead to added costs to you or your insurance company.

Preventative skin care regimen materials including bleach, sunscreen, soap, lotion and emollients will be provided by the Dermatology Research Fund at the Jimmy Fund Clinic.

You will not be charged for the following that are part of this research study:

- Dermatology visit (if you weren't scheduled to see Dermatology as part of your clinic visit)

You or your insurance company will be charged for other portions of your care during this research study that are considered standard of care. You may be responsible for co-payments and deductibles that are standard for your insurance coverage.

If you have questions about your insurance coverage, or the items you might be required to pay for, please call financial services for information. The contact information for financial services:

- Boston Children's Hospital: (617) 355-3397
- Dana-Farber Cancer Institute: (617) 632-3455

The National Cancer Institute provides an online resource to help people participating in cancer clinical trials understand which services their insurance company is required by law to pay. This can be found at the website below.

http://www.cancer.gov or 1-800-4-CANCER (1-800-422-6237)

## G. WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

If you think you have been injured as a result of taking part in this research study, tell the person in charge of this research study as soon as possible. The research doctor's name and phone number are listed in this consent form.

The treating hospital will offer you the care needed to treat injuries directly resulting from taking part in this research. These treatments may be billed to you or your insurance company. You will be responsible for deductibles, co-payments and co-insurance. There are no plans to pay you or give you other compensation for the injury.

You do not give up your legal rights by signing this form.

We will need to collect certain personal information about you for insurance or payment reporting purposes, such as your name, date of birth, gender, social security number or Medicare identification number and information related to this research study. We may be required to report this information to the Centers for Medicare & Medicaid Services. We will not use this information for any other purpose.

If you go to the Emergency Room or to another hospital or doctor it is important that you tell them that you are in this research. If possible, you should give them a copy of this consent form.

## H. WHOM DO I CONTACT IF I HAVE QUESTIONS ABOUT THE RESEARCH STUDY?

If you have questions about the study, please contact the research Investigator or study staff as listed below:

**Dana-Farber Cancer Institute & Boston Children's Hospital**

- Jennifer Huang, MD 617-355-6117

**24-hour contact:** DFCI & BCH: Jennifer Huang, MD at 617-355-6117 or page at 617-355-6000, beeper 2289.

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at DFCI (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study. For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at Dana-Farber Cancer Institute (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study.

## I. RETURN OF RESEARCH RESULTS

Tests done in this research study are only for research and have no clear meaning for your health care. For this reason, your study doctor will not share the results with you.

## J. CLINICALTRIALS.GOV

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

## K. FUTURE USE OF DATA AND SPECIMENS

Your personal information and/or biospecimens collected during this study may be stored and used for future research. Any personal identifiers will be removed, before they are shared, so that the information or samples cannot be linked back to you.

## L. CONFIDENTIALITY

We will take measures to protect the privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data.

Medical information created by this research study may become part of your hospital medical record and may be forwarded to your primary doctor. Information that does not become part of your medical record will be stored in your study file. It may also become part of a research database.

The study team plans to publish the results of this research study and when we do, we may be asked to make the data we collect available to other researchers. We will not include information that identifies you in any publications or to the researchers who request the data to do additional research.

There is a risk that de-identified research data that is shared with outside collaborators may be re-identified. When de-identified data are shared with outside collaborators agreements limit what the outside collaborators can do with the information to help prevent re-identification.

## M. FINANCIAL DISCLOSURES

It is possible that certain researchers on this study may have earned money from, or own some publicly-traded stock in, the company that makes or is developing the study. The amount of money that a researcher may earn and still take part in research is limited by the Harvard Medical School Faculty of Medicine Policy on Conflicts of Interest and Commitment. If you have further questions, please speak with a member of the study team or contact the Dana-Farber Cancer Institute Office of Research Integrity at 617-432-4557 or researchintegrity@dfci.harvard.edu.

## N. PRIVACY OF PROTECTED HEALTH INFORMATION (HIPAA AUTHORIZATION)

The Health Insurance Portability and Accountability Act (HIPAA) is a federal law that requires Dana-Farber/Harvard Cancer Center (DF/HCC) and its affiliated research doctors, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions ("protected health information"). If you enroll in this research study, your "protected health information" will be used and shared with others as explained below.

## 1. What protected health information about me will be used or shared with others during this research?

- Existing medical records, including mental health records.
- New health information created from study-related tests, procedures, visits, and/or questionnaires

## 2. Why will protected information about me be used or shared with others?

The main reasons include the following:

- To conduct and oversee the research described earlier in this form;
- To ensure the research meets legal, institutional, and accreditation requirements;
- To conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm); and
- To provide the study sponsor with information arising from an adverse event or other event that relates to the safety or toxicity of the drug(s) used in the study and for the purpose of this or other research relating the study drug(s) and their use in cancer;
- To better understand the diseases being studied and to improve the design of future studies; and,
- Other reasons may include for treatment, payment, or health care operations. For example, some medical information produced by this research study may become part of your hospital medical record because the information may be necessary for your medical care. (You will also be given a notice for use and sharing of protected health information.)

## 3. Who will use or share protected health information about me?

- DF/HCC and its affiliated research doctors and entities participating in the research will use and share your protected health information. In addition, other DF/HCC offices that deal with research oversight, billing or quality assurance will be able to use and share your protected health information.

**4. With whom outside of DF/HCC may my protected health information be shared?**

While all reasonable efforts will be made to protect the confidentiality of your protected health information, it may also be shared with the following entities:

- Outside individuals or entities that have a need to access this information to perform functions relating to the conduct of this research such as analysis by outside laboratories on behalf of DF/HCC and its affiliates (for example, data storage companies, insurers, or legal advisors).
- The sponsor(s) of the study, its subcontractors, representatives, business partners, and its agent(s): Boston Children's Hospital
- Other research doctors and medical centers participating in this research, if applicable
- Federal and state agencies (for example, the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes. A qualified representative of the FDA and the National Cancer Institute may review your medical records.
- Hospital accrediting agencies
- A data safety monitoring board organized to oversee this research, if applicable

Some who may receive your protected health information may not have to satisfy the privacy rules and requirements. They, in fact, may share your information with others without your permission.

**5. For how long will protected health information about me be used or shared with others?**

- There is no scheduled date at which your protected health information that is being used or shared for this research will be destroyed, because research is an ongoing process.

## 6. Statement of privacy rights:

- You have the right to withdraw your permission for the research doctors and participating DF/HCC entities to use or share your protected health information. We will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure quality of the study. To withdraw your permission, you must do so in writing by contacting the researcher listed above in the section: “Whom do I contact if I have questions about the research study?”
- You have the right to request access to your protected health information that is used or shared during this research and that is related to your treatment or payment for your treatment, but you may access this information only after the study is completed. To request this information, please contact the researcher listed above in the section: “Whom do I contact if I have questions about the research study?”

## O. DOCUMENTATION OF ASSENT

**Signature of participant between age of 10 and 18:** The person doing this research study has explained what will happen to me if I take part in this research study. My signature below means that I want to be in this research study. I can decide not to take part in this research study if I do not want to and nothing will happen to me if I decide I do not want to participate.

_____ _____
Signature of Participant Date

**To be completed by person obtaining assent:**

The assent discussion was initiated on _____ (date).

☐ The information was presented in age-appropriate terms. The minor:

- ☐ Agreed to take part in the study
- ☐ Did not agree to take part in the study

☐ An assent discussion was not initiated with the minor for the following reason(s):

- ☐ Minor is incapacitated
- ☐ Minor is under 10 years of age
- ☐ Other_____

_____

Signature of Individual obtaining assent: _____

Printed name of above: _____

Date: _____

## P. DOCUMENTATION OF CONSENT

My signature below indicates:

- I have had enough time to read the consent and think about participating in this study;
- I have had all of my questions answered to my satisfaction;
- I am willing to participate in this study;
- I have been told that my participation is voluntary and I can withdraw at any time

Signature of Participant or Legally Authorized Representative

Date

Relationship of Legally Authorized Representative to Participant



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**To be completed by person obtaining consent:**

## Adult Participant

The consent discussion was initiated on _____ (date).

Signature of individual obtaining consent: _____

Printed name of above: _____

Date: _____

☐ A copy of this signed consent form will be given to the participant or legally authorized representative.

☐ 1) The participant is an adult and provided consent to participate.

☐ 1a) Participant (or legally authorized representative) is a non-English speaker and signed the translated Short Form in lieu of English consent document:

☐ *As someone who understands both English and the language used by the participant, I interpreted and/or witnessed, in the participant's language, the researcher's presentation of the English consent form. The participant was given the opportunity to ask questions.*

Signature of Interpreter/Witness: _____

Printed Name of Interpreter/Witness: _____

Date: _____

☐ 1b) Participant is physically unable to sign the consent form because:

☐ The participant is illiterate.

☐ The participant has a physical disability.

☐ Other (please describe): _____

*The consent form was presented to the participant who was given the opportunity to ask questions and who communicated agreement to participate in the research.*

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

☐ 2) The participant is an adult who lacks capacity to provide consent and his/her legally authorized representative:

☐ 2a) gave permission for the adult participant to participate

☐ 2b) did not give permission for the adult participant to participate

**To be completed by person obtaining consent:**

## Minor Participant

The consent discussion was initiated on _____ (date).

Signature of individual obtaining consent: _____

Printed name of above: _____

Date: _____

☐ A copy of this signed consent form will be given to the participant or legally authorized representative, or, where the participant is a minor, the participant's parent or legal guardian.

☐ 1) The parent or legally authorized representative gave permission for the minor to participate.

☐ 1a) Parent or legally authorized representative is a non-English speaker and signed the translated Short Form in lieu of English consent document

*As someone who understands both English and the language spoken by the participant, I interpreted and/or witnessed, in the participant's language, the researcher's presentation of the English consent form. The participant was given the opportunity to ask questions.*

Signature of Interpreter/Witness: _____

Printed name of Interpreter/Witness: _____

Date: _____

☐ 1b) Parent or legally authorized representative is physically unable to sign the consent form because:

☐ The participant is illiterate.

☐ The participant has a physical disability.

☐ Other (please describe): _____

*The consent form was presented to the parent or legally authorized representative who was given the opportunity to ask questions and who communicated agreement for the minor to participate in the research.*

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

☐ 1c) The parent or legally authorized representative did not give permission for the minor to participate