Title: Integration of Multimodal Cancer Predisposition Genetic Counseling Practices Within the Pediatric Oncology Setting: Digital Care Plans for Patients With CPS

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Document: Verbal Consent Form

Children's Hospital of Philadelphia

Informed Consent and HIPAA Authorization Form

Study Title:	Integration of Multimodal Cancer Predisposition Genetic Counseling Practices Within the Pediatric Oncology Setting: Digital Care Plans for Patients With CPS
Version Date:	June 6th, 2024
Consent Name:	Verbal Parent and Adult/Young Adolescent Consent and AYA Assent

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You, or your child(ren), may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

In the sections that follow, the word "we" means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child or children, please note that the word "you" refers to your child(ren).

Study Overview

You or your child(ren) (between the ages of 12 and 26 years old) are being asked to take part in this research study because you or your child(ren) have been diagnosed with a cancer predisposition syndrome (CPS). CPS is a genetic syndrome causing increased risk of certain cancers in childhood. The purpose of this study is to create and evaluate digital care plans and text messages to help families manage the medical care involved in their CPS. The care plan is personalized and will describe your specific diagnosis along with your screening and prevention plan. The text messages will remind you of information from your care plan and to schedule and attend medical appointments based on the recommendations in your care plan. Our long-term goal is to improve care for children and adolescents living with CPS.

Study participation will last for about 6 months. If you take part, you will be asked to:

- Complete surveys about your family's understanding of cancer predisposition guidelines
- Receive a digital care plan for your or your child(ren)'s cancer predisposition syndrome
- Enroll in text message reminders of information in the care plan and to schedule and attend medical appointments
- Allow us to review your medical record

The main risks of this study are from the questions in the surveys. These risks include feeling uncomfortable or distressed answering questions. You will not benefit directly

from participating in this study. There are no known physical or legal risks associated with taking part in this study.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time. If you do not choose to take part in this study, you can discuss treatment options with your doctor.

Please see below for additional details about the study.

How many people will take part?

100 families will take part in this study.

What is the current standard of treatment for this disease?

Patients with a cancer predisposition syndrome usually receive verbal education about their diagnosis and medical care plan. This education comes from their doctor and/or a genetic counselor. It may or may not be written.

What are the study procedures?

You will be asked to complete surveys three different times over a 6-month period. Each survey will take about 15 minutes to complete. Tests that are part of your regular, routine medical care will continue to be performed and will not be impacted by your study participation. The study involves the following procedures:

Time 1: You will complete an electronic survey either remotely or in person.

Care Plan & Text Messages: Once enrolled in the study, you will receive a personalized digital care plan and be enrolled in a text message alert system.

Time 2: About three months after enrollment, you will complete an electronic survey either remotely or in person.

Time 3: About six months after enrollment, you will complete an electronic survey either remotely or in person.

Medical Record Review: We will review your medical records to get information about your diagnosis, treatment, follow-up, clinic visits, and results from tests and procedures.

Will I receive any results from the tests done as part of this study?

You will not receive any results from the survey questions asked in this study.

What are the risks of this study?

Although there are no known physical or legal risks associated with taking part in this study, you may experience discomfort or emotional distress when answering questions about your child(ren)'s cancer predisposition syndrome. You do not have to answer any uncomfortable or upsetting questions, and you may stop the study at any time. If needed,

a licensed clinical psychologist is available to assist you with obtaining additional psychosocial support.

Are there any benefits to taking part in this study?

You may benefit by receiving specific guidelines for you or your child(ren)'s CPS and care plan recommendations. The text message reminders may also provide benefit through direct reminders of important steps in medical care. However, we cannot guarantee or promise that you will receive any direct benefit by participating in this study. The knowledge gained from this research may help doctors better understand how to support patients and families with childhood cancer predisposition.

Do you need to give your consent in order to participate?

If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You do not have to take part in order to receive care at CHOP.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

Can the study doctor take you out of the study early?

The study doctor may take you off of the study if:

- You no longer meet enrollment requirements of the study
- New information suggests taking part in the study may not be in your best interests

What choices do you have other than this study?

There are options for you other than this study including:

- Not participating in this study.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you will be collected. This will include information from medical records, procedures, and study questionnaires. Medical records are available to CHOP staff. Staff will view your records only when required as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. Your responses to study questionnaires will be

associated with a number, not your name. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP;
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections;
- The National Institutes of Health who is sponsoring this research.

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

Information that will be collected for this study will be retained for at least 6 years. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years, and it is not possible to know when they will be completely done.

Certificate of Confidentiality (CoC)

A Certificate of Confidentiality (CoC) covers this research. A CoC helps protect your identifiable information.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- No one can be forced to share your identifiable information or biological samples for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

If you consent, your data could be shared for:

- Other scientific research.

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The NIH may need information to assess this project.
- You can still share information about yourself. You can also freely discuss your involvement in this research.

- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform one of the investigators in writing.

Dr. Suzanne MacFarland
The Children's Hospital of Philadelphia
Department of Oncology
34th Street and Civic Center Blvd.
Philadelphia, PA 19104

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications, and doctor visits – will continue to be billed to you or your insurance.

Will there be any additional costs?

There will be no additional costs to you by taking part in this study.

Will you be paid for taking part in this study?

If you participate in this study, you will be compensated for your time and effort via a pre-loaded bank card (hereafter referred to as a ClinCard) or an amazon e-gift card. If you receive payment using a bankcard, the bank will have access to identifiable information. The bank will not have access to any medical information. Payments for participation are as follows:

- Parent(s) and AYA(s) (adolescent/young adult) will each receive $20 for completing study questionnaires prior to receiving their care plan and enrolling in text message reminders.
    - Parent(s) may receive an additional $10 per additional child enrolled
- Parent(s) and AYA(s) will each receive $20 for completing study questionnaires 3 months after implementation of the care plan and text message alerts.
    - Parent(s) may receive an additional $10 per additional child enrolled
- Parent(s) and AYA(s) will each receive $20 for completing study questionnaires 6 months after implementation of the care plan and text message alerts.
    - Parent(s) may receive an additional $10 per additional child enrolled

Who is funding this research study?

The National Institutes of Health is providing funding for this study.

Please ask Dr. MacFarland if you have any questions about how this study is funded.

What if you have questions about the study?

If you have questions about this study or how your data are going to be used, call the study doctor, Dr. MacFarland at (267) 425-1919. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

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.

What will be done with my data when this study is over?

We will use and may share data and/or specimens for future research. They may be shared with researchers/institutions outside of CHOP. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data and/or specimens, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data.

Documentation of Verbal Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

Consent for Proband 1 Participation

_____
Name of Subject 1 (Proband)

The research study and consent form was explained to:

Person Providing Consent (If subject is under 18)	Relation to subject: ☐ Parent ☐ Legal Guardian ☐ Self

Consent for Proband 2 Participation

_____
Name of Subject 2 (Proband)

The research study and consent form was explained to:

Person Providing Consent (If subject is under 18)	Relation to subject: ☐ Parent ☐ Legal Guardian ☐ Self

Consent for Proband 3 Participation

_____
Name of Subject 3 (Proband)

The research study and consent form was explained to:

Person Providing Consent (If subject is under 18)	Relation to subject: ☐ Parent ☐ Legal Guardian ☐ Self

Consent for Proband 4 Participation

Name of Subject 4 (Proband)

The research study and consent form was explained to:

Person Providing Consent (If subject is under 18)	Relation to subject: ☐ Parent ☐ Legal Guardian ☐ Self

Consent for Caregiver Participation

Name of Subject (Primary Caregiver)

The research study and consent form was explained to:

Person Providing Consent	Relation to subject: ☐ Self

Name of Subject (Secondary Caregiver)

The research study and consent form was explained to:

Person Providing Consent	Relation to subject: ☐ Self

The person who provided consent confirmed that all of their questions had been answered and they agreed to their/their child's participation in this research study.

They confirmed that they were legally authorized to consent to their child's participation.

They agreed to let CHOP use and share their child's health information.

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

Documentation of Verbal Child 1 Assent to Take Part in this Research Study

For children capable of providing assent:

I have explained this study and the procedures involved to (P1)_____ in terms he/she could understand and that he/she freely assented to take part in this study.

_____
Person Obtaining Assent

_____ _____
Signature of Person Obtaining Assent Date

For children unable to assent:

I certify that (P1) _____ was not capable of understanding the procedures involved in the study sufficiently to assent to study participation.

_____
Person Responsible for Obtaining Assent

_____ _____
Signature of Person Responsible Date

Documentation of Verbal Child 2 Assent to Take Part in this Research Study

For children capable of providing assent:

I have explained this study and the procedures involved to (P2)_____ in terms he/she could understand and that he/she freely assented to take part in this study.

_____
Person Obtaining Assent

_____ _____
Signature of Person Obtaining Assent Date

For children unable to assent:

I certify that (P2) _____ was not capable of understanding the procedures involved in the study sufficiently to assent to study participation.

_____
Person Responsible for Obtaining Assent

_____ _____
Signature of Person Responsible Date

Documentation of Verbal Child 3 Assent to Take Part in this Research Study

For children capable of providing assent:

I have explained this study and the procedures involved to (P3)_____ in terms he/she could understand and that he/she freely assented to take part in this study.

_____
Person Obtaining Assent

_____ _____
Signature of Person Obtaining Assent Date

For children unable to assent:

I certify that (P3) _____ was not capable of understanding the procedures involved in the study sufficiently to assent to study participation.

_____
Person Responsible for Obtaining Assent

_____ _____
Signature of Person Responsible Date

Documentation of Verbal Child 4 Assent to Take Part in this Research Study

For children capable of providing assent:

I have explained this study and the procedures involved to (P4)_____ in terms he/she could understand and that he/she freely assented to take part in this study.

_____
Person Obtaining Assent

_____ _____
Signature of Person Obtaining Assent Date

For children unable to assent:

I certify that (P4) _____ was not capable of understanding the procedures involved in the study sufficiently to assent to study participation.

_____
Person Responsible for Obtaining Assent

_____ _____
Signature of Person Responsible Date