

# **Informed Consent Form**

**TITLE:** SurvivorLink: Scalability of an Electronic Personal Health Record for Cancer Survivors and Caregivers at Pediatric Cancer Centers

**NCT NUMBER:** NCT03543852

**IRB APPROVAL DATE:** September 19, 2023

## **Informed Consent Form for Caregivers and Young Adults You Are Being Asked to Be in a Research Study**

### **What Is a Research Study?**

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

### **Do I Have to Do This?**

**No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.**

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

### **What Is This Document?**

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

### **What Should I Do Next?**

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. Take time to consider this, and talk about it with your family and friends.

**Emory University**  
**Consent to be a Research Subject**

**Title:** SurvivorLink: Scalability of an Electronic Personal Health Record for Cancer Survivors and Caregivers at Pediatric Cancer Centers

**Principal Investigators:** Cam Escoffery, PhD, Department of Behavioral Sciences and Health Education, Rollins School of Public Health; Ann Mertens, PhD, Aflac Cancer and Blood Disorders Center, Emory University

**Sponsor:** National Cancer Institute

**Introduction**

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you or your child to lose any medical benefits. If you decide not to take part in this study, you or your child's doctor will continue to treat them.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with your friends, family, or healthcare team. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

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 is the purpose of this study?**

You are being asked to take part in this study because you or your child was diagnosed with cancer. Great progress has been made in curing cancer. However, cancer treatment can lead to complications or side effects in some patients. Therefore, life-long follow-up of cancer survivors is suggested to screen for these late-effects, and to receive a Survivorship Care Plan that serves as an individual's guide for long-term follow-up care.

The purpose of this study is to test the effects of a survivorship tool. During the course of this study, you will be asked to register and interact with a tool and complete evaluation surveys.

**What will I be asked to do?**

You will be asked to interact with a survivorship tool and answer 3 or 5 surveys for up to 24 months. We will ask questions about survivorship care and technology use. The surveys will take about 15-20 minutes to complete. We will also collect information from your/your child's medical records regarding their cancer treatments, clinic attendance, and recommended follow-up care. We will be able to see your use of the survivorship tool and will run web analytics on use from all users. Some users of the tool will be invited to participate in a 30-minute interview about their use of and satisfaction with the tool.

**Who owns my study information?**

If you join this study, you will be providing information about your/your child's health. You will not receive any compensation if your information is used to make a new product. If you withdraw from the study, data that were already collected may still be used for this study.

**What are the possible risks and discomforts?**

Possible risks and discomforts that may result from this study include potential loss of privacy and confidentiality. To minimize this risk, we will make sure that only members of the study staff have access to your survey data or medical records, unless these records are otherwise required by law or other Research Offices as described in the **Confidentiality** section. Any reports derived from this data will not be linked to your name, contact information, or any other identifying information.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

**Will I benefit directly from the study?**

This study is not designed to benefit you directly. This study is designed to learn more about the impact of a survivorship tool on survivors' follow-up cancer care. The study results may be used to help others in the future.

**Will I be compensated for my time and effort?**

You will get \$20 for each completed study survey, to compensate you for your time and effort. If you do not finish the study, we will compensate you for the surveys you have completed. You will get \$60 or \$100 total depending on your assigned group, if you complete all study surveys. If you participate in the optional interview, then you will get \$20.

**What are my other options?**

You may choose not to participate in this study. If you do not take part in the study, it will not affect your child's treatment or long-term follow-up at our centers. Talk to your study doctor about your choices before you decide if you will take part in this study.

**How will you protect my private information that you collect in this study?**

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

**Certificate of Confidentiality**

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you or your child.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your or your child's insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you/your child:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

### **Storing and Sharing your Information**

De-identified data from this study may be shared with the research community at large to advance science and health. Data from this study may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you or your child before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you or your child from the information we share. Despite these measures, we cannot guarantee anonymity of your or your child's personal data.

### **Withdrawal from the Study**

You have the right to leave a study at any time without penalty. The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

## **Authorization to Use and Disclose Protected Health Information**

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules."

### **PHI that Will be Used/Disclosed:**

The PHI that we will use or share for the research study includes:

- Name
- Address
- Telephone numbers and emails
- Internet Protocol (IP) address number
- Your/your child's quality of life, control of your/your child's health outcomes, and your/your child's health care use
- Your/your child's medical history, including diagnoses, treatments, and visits
- Your/your child's medical records (date of birth, and results of exams, procedures, and tests that occurred before or during the study)

### **Purposes for Which Your PHI Will be Used/Disclosed:**

We will use and share your PHI for the conduct and oversight of the research study. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

### **Use and Disclosure of Your Information That is Required by Law:**

We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

**Authorization to Use PHI is Required to Participate:**

By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form. If you do not sign this form, you may still use the survivorship tool.

**People Who will Use/Disclose Your PHI:**

The following people and groups will use and disclose your/your child's PHI in connection with the research study:

- The Principal Investigators and the research staff will use and disclose your/your child's PHI to conduct the study.
- Emory may use and disclose your/your child's PHI to run normal business operations.
- The Principal Investigator and research staff will share your/your child's PHI with other people and groups to help conduct the study or to provide oversight for the study.
- The National Cancer Institute (NCI) is the Sponsor of the study. The Sponsor may use and disclose your/your child's PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your/your child's PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your/your child's PHI to make sure the research is done correctly and safely:
  - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
  - Other researchers and centers that are a part of this study.
  - Government agencies that regulate the research including: Office for Human Research Protections; Food and Drug Administration.
  - Public health agencies.
  - Research monitors and reviewer.
  - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your/your child's PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

**Expiration of Your Authorization**

Your PHI will be used until this research study ends.

**Revoking Your Authorization**

If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

SurvivorLink Program  
Rollins School of Public Health  
Emory University  
1518 Clifton Road, NE, 5<sup>th</sup> Floor  
Atlanta, GA 30322

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the main study.

### **Other Items You Should Know about Your Privacy**

Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

### **Contact Information**

Contact Drs. Cam Escoffery at [REDACTED] or Ann Mertens at [REDACTED]:

- if you have any questions about this study or your part in it,
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or [irb@emory.edu](mailto:irb@emory.edu):

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at <http://www.surveymonkey.com/s/6ZDMW75>.

**Consent and Authorization**

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***TO BE FILLED OUT BY SUBJECT ONLY***

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

\_\_\_\_\_  
**Name of Subject**

\_\_\_\_\_  
**Signature of Subject (18 or older and able to consent)**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Time**

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***TO BE FILLED OUT BY STUDY TEAM ONLY***

\_\_\_\_\_  
**Name of Person Conducting Informed Consent Discussion**

\_\_\_\_\_  
**Signature of Person Conducting Informed Consent Discussion**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Time**