Consent and Authorization Document

Research Study Title: Self-Management Intervention for Children with Chronic Medical Complexity

BACKGROUND

You are being asked to take part in a research study because you are a primary caregiver for a child with medical complexity (CMC). This study is voluntary and it is up to you to decide whether or not you want to participate. Before you decide to participate 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 for clarification if there is anything that is not clear or if you would like more information.

The purpose of the study is to test and determine the effectiveness of a novel home monitoring and care coordination smartphone application for children with CMC, called MyChild^{CMC}. MyChild^{CMC} is designed to support caregivers in monitoring common symptoms, including temperature, heart rate, respiratory rate, seizures, agitation, feeding intolerance, pain, and feeling of uneasiness about the child's condition. Nurse care managers will also have access to the data participants entered into MyChild^{CMC} to monitor the child's condition, and will help you and your child's physician make decisions. Using the MyChild^{CMC} to track and monitor these symptoms may facilitate early recognition of impending worsening of your child's condition and enable early intervention to prevent hospital or emergency department visits.

STUDY PROCEDURE

The duration of this feasibility study is 3 months. Half of the participants in this study will be randomly assigned to use the MyChild^{CMC} app to track symptoms, and the other half will be randomly assigned as the control group, continuing with their usual care. We will use a computer to help with randomization and determine which group you will be in.

For both the MyChild^{CMC} user group and the control group, we will ask you to complete a few initial surveys on demographics, baseline quality of life, and caregiver satisfaction.

If you are assigned to be in the MyChild^{CMC} user group, we will help you to download the MyChild^{CMC} app on your smartphone and create an account for you. Then we will teach you how to use the app and enter the requested data including your child's temperature, heart rate, respiratory rate, pain score, feeding, and mental status. The app will remind you to enter in this information once a day for 3 months.

If you are assigned to be in the control group, you will continue caring for your child as usual.

Both MyChild^{CMC} users and control groups will receive two follow-up surveys over the 3 months. The surveys will be similar to the initial surveys, and will be completed online.

RISKS

Possible risks include potential loss of privacy or personal information through the MyChild[CMC] app, and emotional discomfort similar to what you might experience sharing your child's personal information with others.

BENEFITS

While we cannot promise any direct benefits for participating in this study, it may help you improve your ability to monitor your child's condition. In addition, information gathered will help researchers to improve the MyChild[CMC] app and ultimately the quality of care provided to children with chronic medical conditions.

ALTERNATIVE PROCEDURES

You may choose not to participate in this study.

PERSON TO CONTACT

If you have questions, complaints or concerns about this study, or if you think you may have been injured from being in this study, you can contact Dr. Flory Nkoy at either (801) 662-3660 or Dr. Nancy Murphy at (801)-213-3599, Monday through Friday 9am to 5pm.

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

It is up to you to decide whether or not to take part in this study. If you decide to take part you are still free to withdraw at any time and without giving a reason. You can tell us that you don't want to be in this study. You can start the study and then choose to stop the study later. This will not affect the care you receive here at Primary Children's Hospital, or your relationship with your doctor.

COSTS AND COMPENSATION TO PARTICIPANTS

There are no costs for participation.

Both MyChild[CMC] user and control group participants will receive a $40 gift card after enrollment surveys are completed. In addition, $40 gift cards will be sent after each of the 2 follow-up surveys are completed.

In addition, each participant will receive a pulse oximeter (a tool to measure the level of oxygen in the blood, valued at $20) to use during the study. At the end of the study, participants will keep the pulse oximeter for personal use.

If you are randomized to MyChild[CMC] group, you will also receive a basic stethoscope, valued at $5, to help you to measure and record your child's respiratory rate in the MyChild[CMC] app.

The total amount of compensation for this study is $140.

AUTHORIZATION FOR USE OF YOUR CHILD'S PROTECTED HEALTH INFORMATION

Protected health information used in this study will be your child's information, and not your health information as the caregiver. Signing this document means you allow us, the researchers for this study to use some information about your child's health for this research study. If we share your child's information with groups outside the research team, we will not include information that might identify your child.

This is the information we will use and include in our research records for your child: Patient Medical Identification Number, Name, Contact Information, Patient Visit Identification Number, Admit Date, Discharge Date, Date of Birth, Age, Sex, Race, Primary Care Provider, Insurance, and Hospital/emergency department Readmissions.

How we will protect and share your child's information:

- We will do everything we can to keep your child's information private but we cannot guarantee this. The study information will be separated from personal identification information and each record assigned a study identification number, and stored independently on a password-secured and encrypted computer in a locked office at Primary Children's Hospital. We will allow the information without identifiers to be used by the study team as needed to conduct the study, always maintaining password security and encryption.

- In order to conduct this study as described in this form, the research records may be reviewed by others who are working with us or who oversee research at the University of Utah:
    - Members of the research team and *University of Utah Health Sciences Center, Primary Children's Hospital*
    - The University of Utah Institutional Review Board (IRB), who reviews research involving people to make sure the study protects your rights;
- We may need to disclose information to others if required by law. If we are required to share your information with groups outside of University of Utah Health Sciences Center and Primary Children's Hospital, 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 your child's health, you should not be part of this research. If you choose not to participate, you can continue to receive health care services at University of Utah Health Sciences Center and Primary Children's Hospital as you have in the past.

What if I decide to Not Participate after I sign the Consent and Authorization Form?

You can tell us anytime that you do not want to be in this study and do not want us to use 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, and you 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.
You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

As the study progresses, we may contact you in the future to participate in future studies. Please indicate your decision of whether you would like to be contacted for future studies by initialing below. No matter what you decide to do, your decision will not affect your participation in this study or your child's medical care.

May we contact you regarding future studies related to this study as the project progresses?

_____ Yes _____ No (Please initial)

CONSENT:

By signing this consent form, I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to participate in this research study and authorize you to use and disclose health information about my child for this study, as you have explained in this document.

_____
Participant's Name

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining Authorization and Consent

_____ _____
Signature of Person Obtaining Authorization and Consent Date