Ann & Robert H. Lurie
Children's Hospital of Chicago

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Patient Name:
MRN:

Adolescent Agreement to Take Part in a Research Study

Study Name: Using Information Technology to Improve Outcomes for Children Living with Cancer Research Plan (SyMon-SAYS)
Funded by: National Institutes of Health
Name of Study Doctor/Researcher: Jin-Shei Lai, Ph.D. at Northwestern University and Alicia Lenzen, M.D. at Ann, and Robert H. Lurie's Children's Hospital of Chicago

We want to tell you about a research study at Lurie Children's and NU/NMH. Research studies help us find better ways to take care of and treat children. Taking part in a research study is voluntary. It is your choice to take part in this research study.

Why is this study being done?
We are asking you to be in this research study because you are between the ages of 8-17 years old with cancer. This study aims to develop and evaluate the effectiveness of a symptom monitoring program (Symptom Monitoring & Systematic Assessment and Reporting System in Young Survivors, SyMon-SAYS) for young children with cancer throughout their treatment continuum, from the time a patient starts therapy through long-term survivorship. By having young teenagers and parents regularly reporting their symptoms via the SyMon-SAYS, this program may enable timely intervention and lessen the impact of symptom burden or your well-being.

We are asking you to be in this research study because we want to learn more about your cancer type.

What will happen in this study?
After you complete a series of surveys regarding your symptom severity, barriers you perceive to managing these symptoms, and your well-being, your will be randomly assigned to Group A or B by using a computer-based data management system. You will be informed which group you are assigned to. The surveys that you will complete are:

- Symptom Management Barriers Questionnaire
- Patient-Reported Outcomes Measurement Information System (PROMIS) measures
- NIH Toolbox Self-efficacy
- Health Literacy Assessment Using Talking Touchscreen Technology short form

If you are assigned to the Group A, you will complete a nine-item symptom survey by logging into the SyMon-SAYS program via the Epic MyChart patient portal every week for 16 weeks.

If you assigned to the Group B, you do not need to anything other than your usual care during weeks 1-8. Starting at the week 9, you will report how you feel by completing a nine-item survey by logging into the SyMon-SAYS program via the Epic MyChart patient portal every week for 8 weeks.

Approved by IRB on: 9.9.2024
IRB Approval Expires on: 8.31.2025
Lurie Children's IRB#: 2019-3018
Stamped by: LR

Our study team will show you how to create a MyChart account if you do not have one yet, install the MyChart app on your smartphone, and/or to access it on your personal computer or tablet. If you prefer not to use your own phone, we will provide you a smartphone during the study period for you to access your MyChart account.

You will complete surveys that is similar to those you completed at the beginning of the study at the week 8 and week 16 while you were in the clinic. If you prefer, you can also complete the surveys at home by accessing the study website. These surveys are:

- Symptom Management Barriers Questionnaire
- Patient-Reported Outcomes Measurement Information System (PROMIS) measures
- NIH Toolbox Self-efficacy
- Program evaluation (EXIT Survey; 16-week only)

During the weeks that you are assigned to complete weekly symptom surveys, your treating nurse or doctor may call you if they are concerned about your reports. You will be given a report showing your weekly symptom scores at week-8 (Group A only) and week-16 prior to meeting with your treating doctor. This report is also available in your medical records that you can review it any time by accessing your MyChart account. You are encouraged to discuss the symptom reports with your doctor.

What are the bad or harmful things that could happen in this study?
There are no physical risks to participating in this project. Some of the questions asked may be mildly upsetting to you since they might reflect issues that are difficult to talk about. In the rare instance that you become extremely upset after answering the questions, you will have the option to take a break or stop if you feel it necessary. If you choose not to continue the study, it will in no way affect your treatment.

What are the good things that could happen in this study?
There are no direct benefits to you for participating in this study. However, the information you provide may help doctors provide better quality of care to other people in the future. You may also find the questions are interesting to answer.

What other options are there?
There are no alternatives to this project other than to not participate. If you choose not to participate, it will not affect your regular treatment at Ann and Robert H. Lurie Children's hospital of Chicago.

Who will see your information?
We will keep your information private. It will only be shared with those carrying out the study, paying for the study, or overseeing the study.

Will there be payment or gifts for being in this study?
You and your parent will be paid $20 (SyMon-SAYS system and report development) or $75 (SyMon-SAYS trial) for your participation in the project in the form of cash at the end of the study.

Who can answer questions about this study?
You can ask your study doctor, nurse or other people working with them on the study
You can ask Dr. Alicia Lenzen or Dr. Jin-Shei Lai anything about the study. If you are not happy with this study and want to talk with someone else, not the study doctor or the people working with the study doctor, you may contact the IRB Office by telephone at (312) 503-7110 or by email at IRB@luriechildrens.org.

We will tell you if we learn new information that may make you change your mind about being in this study.

If you do not want to be in this study, that is okay.

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Signatures
Participant Signature:

By signing this form, I affirm: 1) I have read this form. 2) The research has been explained to me. 3) All of my questions have been answered. 4) I give my assent to take part in this research study.	
Signature of Adolescent or Legally Authorized Representative (LAR):	Date:
Printed Name:	

Signature of Authorized Person Obtaining Assent:

I certify that I have explained the above to the participant/LAR and the signature was obtained voluntarily.	
Signature:	Date:
Printed Name:	

When it is not possible to obtain written assent:
To be completed by the Person Obtaining Assent.

Initials	This adolescent is unable to given written assent but has given verbal assent to participate in the study.

Initials	This adolescent is unable to give written or verbal assent. The study PI (or delegate) has obtained a waiver of assent from the IRB Chair. Note: To request a waiver, e-mail IRB@LurieChildrens.org.

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You can still participate in the study if you do not agree to the optional research below.

What are the purpose and procedures of this optional research?
The purpose of this optional research is to understand how you and your health care providers communicate about your answers about your symptoms from the SyMon-SAYS system and what it was like to participate in the SyMon-SAYS project.

This optional research involves a telephone interview. The interview will be audio recorded for the purpose of transcription so that all your input can be captured accurately. The transcriptions will not include any identifying information about you, and your name will not be reported in connection to your comments in any publications or to your clinicians. The transcription from the interview will only include the study ID that will be assigned to you once you consented to the study.

What information or samples will be kept for this optional research?
The audio recording of your telephone interview will be saved. In any reporting of this research, all information identifying you will be removed.

Who will have access to my information or samples for this optional research and how will it be kept private?
The audio recording will be stored on a secure, password-protected server. Only members of the study team will have access to the recording.

Can I take back (withdraw) my permission for this optional research?
Yes, if you wish to take back (withdraw) your permission, you can contact Dr. Alicia Lenzen at 312-227-4090 or Dr. Jin-Shei Lai at 312-503-3370, or you may contact the IRB Office by telephone at (312) 503-7110 or by email at IRB@luriechildrens.org.

Please **initial** next to your choice below regarding the optional testing.

Initials	YES, I agree to allow the audio recording of my telephone interview with a member of the study team.
Initials	NO, I do not agree to allow the audio recording of my telephone interview with a member of the study team.

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