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

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Note: Label required for cover page, but is optional for other pages if the following information is provided:
Patient Name:
MRN:

Parent Permission for a Child to Participate in a Research Study

Study Name: Using Information Technology to Improve Outcomes for Children Living with Cancer Research Plan
Funded by: National Institutes of Health
Name of Researcher (referred to as the study doctor): 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

This consent form describes a research study for which your child might qualify at Ann & Robert H. Lurie Children's Hospital of Chicago ("Lurie Children's") and Northwestern University ("NU"). Research studies help us learn more about conditions and develop better treatments for symptoms that your child may experience. Taking part in a research study is voluntary. It is your choice to allow your child to take part in this research study. Please read this consent form and ask questions about anything you do not understand. You may talk to others such as your family or healthcare providers before you decide to allow your child to take part in this study. The study staff will also explain the study to you and answer any questions that you may have. Your decision will not affect your child's regular care.

What are the purpose and goals of this study?
Parents of children age 8-17 years old with cancer are invited to participate in this research study. 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 children with cancer throughout their treatment continuum, from the time a patient starts therapy through long-term survivorship. By having children and parents regularly reporting children's symptoms via the SyMon-SAYS, this program may enable timely intervention and lessen the impact of symptom burden on children's well-being.

If I agree to have my child take part in this study, what would my child and I need to do?
After you and your child complete a series of surveys regarding your child's symptom severity, barriers you perceive to managing these symptoms, and your child's well-being, your child will be randomly assigned to Group A or B by using a computer-based data management system. You and your child will be informed which group your child is assigned to. The surveys that you and your child 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 your child is assigned to the Group A, you and your child 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 your child is assigned to the Group B, you and your child do not need to anything other than your child's usual care during weeks 1-8. Starting at the week 9, you and your child will report how your child feels by completing a nine-item survey by logging into the SyMon-SAYS program via the Epic MyChart patient portal every week for 8 weeks.

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

What are the risks, side effects, or discomforts related to the 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 benefits from 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 does my child have?

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

What if my child's study doctor or I do not think my child should stay in the study?
Your child can stop taking part in this study at any time. Your choice will not affect your child's regular care.

Returning Study Results:
The study team will not return study results to you and your child. However, you can access results of the symptom survey that you and your child complete every week by accessing your child's medical record in Epic. You can also ask the study team any questions you have about study results.

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

Planned Sharing of your Child's Information:
If you agree to let your child take part in this study, you also give permission to the use and sharing of your child's information. This permission lasts until the study is completed.

A study ID will be assigned. Only Dr. Lai and the coordinator have access to the names associated with each ID. Participants' names will not be included in any dataset.

The information that may be collected and shared will include your child's:

- Personal and health information
- Past and present medical records
- Records from study visits and phone calls

The study staff, including Lurie Children's employees and Medical Staff, the Institutional Review Board (IRB) of this hospital, Northwestern Memorial Hospital (NMH), Northwestern University (NU), Shirley Ryan AbilityLab, Northwestern Medical Faculty Foundation (NMFF), the Northwestern Memorial Physicians Group (NMPG) may use your child's information and share it with:

- The study sponsor, National Institutes of Health (NIH), and those working with the sponsor.
- The Institutional Review Board (the committee that is in charge of protecting the rights of all adults and children who take part in research studies).
- Your child's other providers and their staff directly involved in your child's care, if your child's provider is a part of the Lurie Children's electronic health information exchange.

- The Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA), or other government offices.

The results of this study will be made available to the NIH. Also, your child's hospital records may be made available to employees from NIH. Your child's name will not be included in any written or verbal reports of study results.

These are the only people to which we will give your child's information. We cannot guarantee that those listed above will not share it with others without your permission.

When your child turns 18, the study team will ask your child if it is okay to keep and use their information. Without this permission, information that can be linked to your child will not be kept or used.

What if I decide not to give permission to use and give out my child's information?
If you decide not to allow the release your child's information, your child will not be able to take part in this study. If you give permission to the use of your child's information, you can withdraw it at any time. Your request should be in writing and sent to the study doctor. The study team can still use any information collected before you tell them to stop.

Can I review or copy my child's information?
You cannot see your child's study records while the study is ongoing. However, any testing that relates to your child's medical care will be put in your child's medical record. You still have a right to request a copy of your child's medical record and tests related to regular medical care that is given during the same time as the study.

Will my child's information be used in future research studies?
The study team may share your child's information for future research. They will remove identifiers such as your child's name and other information that can be linked to your child before this is done. The study team and other researchers may use this for other studies without getting consent from you or your child.

Costs Related to this Study:
There are no study related costs to you or your insurance company.

Payment for Taking Part in this Study:
You (or your child) will be paid $20 (SyMon-SAYS system and report development) or $75 (SyMon-SAYS trial) for their participation in the project in the form of cash at the end of the study. The Information provided by the participants for the receipt of their compensation is stored in a separate excel spreadsheet and kept separately from the record of the interview.

Your and Your Child's Rights When Taking Part in this Study:

If you agree to have your child take part in this study, you are not giving up any of your or your child's legal rights. Your child can stop participating in this study at any time. Your choice will not affect your child's regular care.

Additional Information:

Who can answer my questions about this study?

If you or your child has any questions, contact the study doctor, Dr. Alicia Lenzen, 312-227-4090 during a workday, at night or on weekends.

If you have questions about your child's rights or if you have a complaint, you can call the IRB Office at (312) 503-7110; or via email at IRB@luriechildrens.org.

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

You will be given a copy of this consent form. A copy will also be placed in your child's medical record.

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Patient Name:
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Signatures:

Printed Full Name of Child:

Parent/LAR 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. I give my consent for my child to take part in this research study.	
Signature of Parent or Legally Authorized Representative (LAR):	Date:
Printed Full Name:	
Relationship to Child:	

Signature of Authorized Person Obtaining Consent:

I certify that I have explained the above to the parent(s)/LAR and the signature(s) was obtained voluntarily.	
Signature:	Date:
Printed Full Name:	

Signature of Interpreter/Witness*:

☐ Not applicable, no interpreter used.
I attest that the study information has been presented to the parent/LAR in their native language.
Signature of Interpreter/Witness:
Printed Full Name or Unique Phone ID/Company Name:

Your child 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, your child and your child's health care providers communicate about your child's answers about your child's symptoms from the SyMon-SAYS system and what it was like to participate in the SyMon-SAYS project.

This optional research involves two telephone interviews, one with you and one with your child. The interviews 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 or your child, and your and your child's names will not be reported in connection to your comments in any publications or to your child's clinicians. The transcription from the interview will only include the study ID that will be assigned to your child once he/she has consented to the study.

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

Who will have access to my child's 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 or Dr. Jin-Shei Lai 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 to audio record my child's telephone interview with a member of the study team.
Initials	NO, I do not agree to allow the audio recording of my child's telephone interview with a member of the study team.

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

Note to Investigators: When obtaining consent from a non-English speaking parent/LAR

When a study-specific translated consent document is not available, a translated "short form" (available in several languages on the IRB website) may be used, in combination with a verbal presentation of study information (as outlined in this English consent) with the aid of an interpreter.

a. *The consent process must be witnessed by an individual who is fluent in both English and the language understandable the subject. The interpreter may serve as the witness and should sign both the English consent document and short form.*

b. *The parent/LAR should sign the short form (in the language they understand).*

c. *The investigator and/or study staff authorized by the IRB to obtain consent must sign the approved English version of the consent form.*

d. *A copy of both the IRB-approved English consent form (i.e., the summary) and the translated version of the short form must be given to the parent/LAR.*