VUMC Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Alison Carroll, MD **Revision Date: 4/21/2022**
Study Title: Development and Evaluation of a Heath Literacy-Informed Communication Intervention for Discharge Medication Counseling in Hospitalized Children
Institution/Hospital: Monroe Carell Jr. Children's Hospital at Vanderbilt, Vanderbilt University Medical Center

Name of participant: _____ Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
You are being asked to take part in this research study because your child is being discharged from our hospital with a prescription for a liquid medication. Medication errors are a common cause of heath care-related adverse events (negative effects of your child's medical treatment) and may include decreased effectiveness of the medication (from not enough medicine) or unpleasant or even harmful side effects (from too much medicine).

The goal of this study is to find ways to better prepare caregivers to administer liquid medications at home to improve medication safety and medication adherence. The benefits include helping researchers find the optimal communication strategies to use with caregivers to teach them about their child's medications.

We are planning to enroll about 200 caregivers for this study. This is a randomized study which means that half of the participants will receive an intervention (enhanced discharge communication). The other half of participants will not receive the intervention. All participants will receive standard of care.

We will ask you to complete a brief survey about yourself and your child before you leave the hospital. We will collect your contact information (e-mail address and/or phone number) to help with communication for the follow-up survey 48 to 72 hours after your child is discharged home from the hospital. About 2 to 3 days after your child leaves the hospital we will send you a survey to complete on your phone through an application called myCap. This survey will be about your child's discharge medications and the instructions you received in the hospital about how to give the medicine at home. The initial surveys in the hospital should take no more than 10 minutes and the follow-up survey should take about 20 minutes. You will be provided with a $25 check if you complete the study.

None of the information we will collect will be a part of your child's medical record. What you say will be studied to help us find out more about how we can improve teaching about the medicines that we send children home

from the hospital with. If you decide not to take part in this research, your decision will have no impact on your child's health care.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because your child is being sent home from the hospital with at least 1 liquid medication to continue taking at home.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether you still want to be in this study.

Side effects and risks that you can expect if you take part in this study: There are no anticipated side effects for participating in this study. If the study team discovers a medication dosing error during the follow-up survey you will be told about the error and instructed on the medication dose per your child's medical record. Any further questions will be directed to your child's usual physician for clarification. There is a potential loss of confidentiality but this will be minimized by assigning a study identification number to you and if communicating via e-mail only including one participant per e-mail.

Procedures to be followed and approximate duration of the study:

In-Person Survey: Before your child leaves the hospital, we will ask you questions about your child's current hospitalization and basic questions about yourself. We will also ask you to take a survey to help us learn how well caregivers can understand the medical information that doctors give them. You can skip any questions you do not want to answer. If you are in the intervention group, we will then review the medications that your child's doctor has prescribed for them to take when they leave the hospital. This will take about 10 minutes.

Discharge communication: All participants will receive standard discharge communication about discharge medication use. Participants that are randomized to the intervention group will also receive enhanced discharge communication. This will include showing you how to administer the medication and we will provide you with a written instruction sheet about the medication to take home. This will take about 10 minutes.

Medical record review: After your child goes home, we will review his/her medical record to gather additional information about the medications your child was prescribed to take at home including the name of the mediation, the dose, the frequency, and start and stop dates. We will also review your child's medical diagnoses in the medical chart and other details of their care.

Follow-up Survey: We will send you a survey to complete 2-3 days after your child leaves the hospital through a secure, HIPPA-compliant application on your phone called myCap. You can complete the entire survey on your phone. As a part of this survey we will ask you to take a picture of a dose of the medicine that you are giving your child in a syringe. You will be able to take the picture and send it to research staff securely through the myCap application on your phone. The myCap application is free to download. During the myCap follow-up survey, we will ask you details about your child's medicine and about the teaching you received in the hospital about your child's medicine. This will take about 20 minutes. You can skip any questions you do not want to answer.

Expected costs: There is no cost to you for taking part in this study.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury. There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Good effects that might result from this study:
There may be no direct benefits to you for participating but your answers will help us improve how we talk to caregivers about their child's medicines when they leave the hospital. This may result in less stress and confusion about how to give your child medicines at home.

Payments for your time taking part in this study:
You will receive a $25 check upon completion of the study.

What happens if you choose to withdraw from study participation?
If you choose not to participate or to withdraw before completing participation, there will be no negative consequences. You may participate in other future research studies, and it will have no effect on your ability to receive services to which you are entitled.

Contact Information. If you should have any questions about this research study or possibly injury, please feel free to contact **Alison Carroll, MD** at **615-875-5025** or email her at **alison.carroll@vumc.org** or my Faculty Advisor, **Derek Williams, MD** at **615-322-2744**.

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study: You will not be removed from the study by the study team unless you request to be removed.

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Confidentiality:
All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. We will do our best to keep all your personal information private and confidential. You will be identified by a number and not by name in all study materials. The personal information that will be collected from you will be stored in a password-protected and HIPAA-compliant secure web-based database. All computers used to access the secure database are kept safely behind locked doors and use passwords. When e-mailing with you we will only include a single participant.

Privacy:
Your information may be shared with Vanderbilt of the government, such as the Vanderbilt University Institutional Review Board, Federal Government Office for Human Research Protections, if you or someone else is in danger or if we are required to do so by law.

Study Results: Study results will not be shared with research participants. Your child's information will be securely stored in a HIPAA-approved database only accessible to study personnel.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

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How long will your information be used or shared?

Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?

You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title