Children's Hospital of Philadelphia

Informed Consent Form

Study Title: **Transfusion Recommendations Implemented in the PICU (TRIP)**

Version Date: May 22nd, 2023

Consent Name: Interview Consent v2

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You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

In the sections that follow, the word "we" means the study doctor and other research staff.

Study Overview

You are invited to participate in a research study to evaluate the implementation of computerized decision support tools that are intended to improve compliance with blood transfusion guidelines for PICU patients. We are seeking the perspectives of providers and leaders to help with this evaluation.

You are being asked to take part in this research study because you work in the PICU, hold a leadership position in the PICU or the hospital, or helped implement the computerized decision support tools.

The purpose of this study is to evaluate the implementation of computerized decision support tools that are intended to improve compliance with blood transfusion guidelines for PICU patients.

If you agree to take part, your participation will last for 30-45 minutes and will involve answering questions about implementing and using the computerized decision support tools in the PICU. At the end of the interview we will ask if you are willing to be contacted in case we need to clarify one of your answers, however this is not anticipated.

The main risks of this study are from the loss of confidentiality, but there are no foreseeable psychological or physical risks. Your decision whether or not to participate in this study will not be shared with your supervisor and will not have any effect on your performance evaluation or employment status.

You will not benefit directly from participating in this study. We anticipate your input will assist in the optimization of transfusion practices and use of computerized clinical decision support tools in the PICU.

> If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you have the right to withdraw your consent or discontinue participation at any time without penalty.

How many people will take part?

About 60 people will take part in the study, including approximately 30 participants from CHOP.

What is involved in the study?

If you agree to participate in the study, you will complete an interview with a study team member on a web-based video call (e.g. Microsoft Teams or Zoom). The interview is anticipated to take 30-45 minutes.

What are the study procedures?

A study team member from Stanford University will ask you questions about your experiences and opinions around implementing and using the computerized decision support tools related to blood transfusions in the PICU. You have the right to refuse to answer particular questions.

If you participate in an initial interview, you will be invited to participate in an interview 6 months later. You are not required to complete the second interview. Likewise, if you choose not to complete an interview at this time, you are still eligible to complete an interview in 6 months.

What will be done with my data during this study?

Your interview will be audio recorded and transcribed for analysis. The audio recording will be de-identified and stored on password-protected, encrypted media. Only study staff will have access to the information provided in this interview. The recording will be destroyed once the study is complete. Study findings will be presented in aggregate; individuals will not be identified any presentations or publications. De-identified quotes may also be used in research papers or presentations.

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. The main risks of taking part in this study are discussed below.

Risk of Loss of Confidentiality

As with any study involving collection of data, there is the possibility of breach of confidentiality of data. Every precaution will be taken to secure participants' personal information to ensure confidentiality.

At the time of participation, each participant will be assigned a study identification number. This number will be used on data collection forms, audio, transcription and analysis files. A separate list will be maintained that will link each participant's name to the study identification number for future reference and communication.

Are there any benefits to taking part in this study?

There will be no direct benefit to you from taking part in this study. The knowledge gained from this study may help optimize transfusion practices and use of computerized clinical decision support tools in the PICU.

Do you need to give your consent in order to participate?

If you decide to participate in this study, you must verbally give your consent. A form documenting your verbal consent will be kept as a record.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your employment. If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

Can the study team take you out of the study early?

The study doctor may take you out of the study if the study is stopped or you cannot meet the requirements of the study.

What choices do you have other than this study?

There are options for you other than this study including participating only in a survey that covers similar topics instead of completing an interview and not participating in this study.

Additional Information

Financial Information

Will you be paid for taking part in this study?

Participants will be paid $10 as a gift card for their time and effort.

Who is funding this research study?

The Agency for Healthcare Research and Quality (AHRQ) is providing funding for this study.

What if you have questions about the study?

If you have questions about this study or how your data are going to be used, call the study doctors, Dr. Woods-Hill at (727) 385-5870 (CHOP Investigator) or Dr. Steffen at (650) 736-1501 (Stanford Investigator).

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

What will be done with my data when this study is over?

We will use and may share data for future research. They may be shared with researchers/institutions outside of CHOP. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your data.

Documentation of Verbal Consent to Take Part in this Research Study

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Name of Subject

The person who provided consent confirmed that all of their questions had been answered and they agreed to their participation in this research study.

They agreed to let CHOP use and share their interview information.

_____ _____

Person Obtaining Consent | Signature of Person Obtaining Consent

_____

Date