Children's Hospital of Philadelphia

Informed Consent Form

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

Version Date: November 25th, 2024

Consent Name: Practice Impact Survey Consent v3

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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 on the implementation of computerized clinical decision support tools to improve use of blood transfusion recommendations in the pediatric intensive care unit (PICU). The study team would like to better understand the perspectives of PICU providers about potential delays in providing necessary transfusions due to the blood transfusion recommendations and transfusion clinical decision support tool.

You are being asked to take part in this research study because you work in the PICU as an attending or fellow physician.

The purpose of this portion of the study is to assess the impact of the clinical decision support tool and the transfusion recommendations on practice. Specifically, we want to know about instances when these interventions caused delays in necessary transfusions. We are seeking the perspectives of providers to help with this evaluation.

If you agree to take part, your participation will last for less than 5 minutes and will involve answering survey questions about your experience using the recommendations and clinical decision support tool the prior week.

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 100 people will take part in the study, including approximately 70 participants from Stanford.

What is involved in the study?

If you agree to participate in the study, you will complete an online survey. The survey is anticipated to take less than 5 minutes.

What are the study procedures?

You will complete multiple choice and free response questions about your opinions about how using the blood transfusion decision support tool and recommendations impacted care in the PICU the prior week. You have the right to refuse to answer particular questions.

What will be done with my data during this study?

Your survey responses will be collected in a secure web-based data portal (REDCap). You will be asked to identify the institution you work in, and your role on the PICU but will not provide any other identifying information. Study findings will be presented in aggregate; individuals will not be identified in 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.

Risk associated with survey completion

There are no physical risks but you might experience momentary embarrassment or discomfort. You do not have to answer any questions that make you too uncomfortable.

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 survey will be assigned a study identification number. This number will be used on data collection forms and analysis files. Your name or other identifying information will not be linked to your survey responses.

What about privacy and confidentiality?

We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required

by law. People from oversight agencies and organizations such as the Department of Health and Human Services, Office for Human Research Protections may also look at your study records.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

By law, Stanford is required to protect your private information. The investigator and staff involved in the study will keep your private information collected for the study strictly confidential.

At the time of participation, each survey will be assigned a study identification number. This number will be used on data collection forms and analysis files. Your name or other identifying information will not be linked to your survey responses.

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?

By completing and submitting this survey, you acknowledge that you have reviewed this consent and agree to participate in this study.

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 to participate in this study including participating future surveys or interviews that covers similar topics, and not participating in this study.

Additional Information

Financial Information

Will you be paid for taking part in this study?

Participants will not be paid for their time or effort to complete surveys.

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 Stanford. 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.

Your completion of the survey implies your voluntary consent to participate in the research.

We greatly appreciate your willingness to complete this survey.