Children's Hospital of Philadelphia

Informed Consent and HIPAA Authorization Form

Study Title: Developing and Implementing a Discharge Stewardship Intervention for Pediatrics: Improving Antibiotic Use at Transition from Hospital to Home (DISCO)

Version Date: April 6, 2022

Consent Name: Parental Permission/Patient Consent Form

Principal Investigator: Jeffrey Gerber Telephone: 267-426-8775

You, or your child, 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. If you are a parent or legal guardian who is giving permission for a child, please note that the word "you" refers to your child.

Study Overview

You or your child are being asked to take part in this research study because you have been admitted and diagnosed with a common childhood infection.

The purpose of this study is to find out if new guidelines and recommendations for antibiotics can improve how clinicians prescribe antibiotics for patients leaving the hospital.

If you agree to take part, your participation will last for less than one month and will involve a general wellness tracker, for 3 days post-discharge, and two brief surveys after you leave the hospital, one each at 1- and 3-weeks post-discharge. The wellness tracker will take less than 1 minutes and each follow-up survey will take about 5-10 minutes of your time.

The main risks of this study are from follow-ups and the possibility of a breach of confidentiality. 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.

You will not benefit directly from participating in this study.

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 can leave the study at any time. If you do not choose to take part in this study, you can discuss treatment options with your doctor. You may also be eligible for a different research study.

Please see below for additional details about the study.

How many people will take part?

About 5,600 participants will take part in the study, including approximately 1,400 participants from CHOP.

What are the study procedures?

Some of the procedures in this study will be repeated several times. Tests that are part of your regular, routine medical care will continue to be performed. The study involves the following tests and procedures.

Collection of demographic information: During the enrollment survey we will be asking parents/caregivers to answer questions about their employment status and their highest level of education.

Medical Record Review: We will review your medical records throughout the study to collect information about your medical history, current health, diagnosis, treatment, medications, and results of clinical tests that have been performed while you are in the hospital, and other information about your hospital stay. We will also collect information about your age, race, gender, and ethnicity. If your child will attend follow-up visits at a medical facility other than CHOP, we will ask for the facility's name and address during your follow-up survey. You will also sign a HIPAA release form after this consent form. This is so we can get permission to obtain your follow-up medical records from that facility.

Survey follow-up: You will be contacted via email, text message or telephone at about 1 week after your discharge date for the first survey, and at about 3 weeks after your discharge date for the second survey. We will ask you about any side effects or illnesses you may have experienced and about any changes to the medications your doctor prescribed.

Wellness tracker: You will be contacted via email, text message or telephone a 1 question survey about your child's illness. The survey will be sent on the third day after discharge and during your 1- and 3-week follow-up survey.

What will be done with my data and specimens during this study?

During the study, we will collect data from you. By agreeing to participate in the study, you agree to give these data to CHOP for research purposes.

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 medical record review:

As with any study involving the 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, blood samples, tissue specimens, and in the database instead of names and other private information. A separate list will be maintained that will link each participant's name to the study identification number for future reference and communication.

Risk of follow-up:

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.

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 doctors determine the effectiveness of the guidelines and recommendations for antibiotics in improving antibiotic prescribing appropriateness for patients who leave the hospital.

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

If you decide to participate in this study, you must sign this form. A copy will be given to you to keep 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. You do not have to take part in order to receive care at CHOP.

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 doctor take you out of the study early?

The study doctor may take you off of the study if you are admitted for more than 7 days, if you are transferred to the intensive care unit for more than 48 hours during your stay, if you get diagnosed with a complex chronic condition during your stay, or if you are discharged without antibiotics for the condition of interest. If this happens, you will receive notice of your ineligibility and will not receive the wellness tracker, follow-up surveys, or compensation.

What choices do you have other than this study?

There are options for you other than this study, including not participating in this study.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you will be collected. This will include information from medical records, procedures, interviews, and tests. Information related to your medical care at CHOP will go in your medical record. Medical records are available to CHOP staff. Staff will view your records only when required as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is

required or allowed by law. 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.

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.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP.
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.
- The Data Coordinating Center at CHOP.
- The Agency for Healthcare Research and Quality, who is sponsoring this research.

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. Jeffrey Gerber
Children's Hospital of Philadelphia
Division of Infectious Diseases
Roberts Center for Pediatric research
2716 South Street, Rm 10364
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In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications, and doctor visits – will continue to be billed to you or your insurance.

Will there be any additional costs?

You may incur additional mobile charges if you choose to have the surveys sent via text to your mobile device.

Will you be paid for taking part in this study?

Parents will receive a $25 gift card for their time and effort in taking part in this study. This will be given to them once after the two follow-up surveys. The gift card will be disseminated via ClinCard. If you receive payment using a bankcard, the bank will have access to some personal information in orer to process your payment. The bank will not have access to any medical information.

Who is funding this research study?

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

What if you have questions about the study?

If you have questions about this study or how your samples/data are going to be used, call the study doctor, Dr. Jeffrey Gerber at 267-426-8775. You may also talk to your own doctor if you have questions or concerns.

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. The data 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 the data. We will remove identifiers from your data, which means that nobody who works with the data 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.

OPTIONAL: Authorization to Use and Disclose Health Information for the Research

This authorization only applies if your child attends follow-up visits at a medical facility outside the CHOP network. This is so we can get permission to obtain information from medical records outside of CHOP including all information for any visits within 3 weeks of discharge. This section is optional and will not affect your participation in the study.

_____ (initials) I agree to have the study team contact my child's healthcare provider for the DISCO study.

_____ (initials) I do not wish to take part in this optional part of the research.

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to your child's participation. You are also authorizing the use of your/your child's health information as discussed above. If you don't agree to the collection, use and sharing of health information, you cannot participate in this study. **NOTE:** *A foster parent is not legally authorized to consent for a foster child's participation.*

Consent for Child's Participation

Name of Subject	
Name of Authorized Representative	Relation to subject: ☐ Parent ☐ Legal Guardian
Signature of Authorized Representative	Date

Consent for Parent/Guardian participation

Name of Parent/Guardian	
Signature of Parent/Guardian	Date

Child Assent to Take Part in this Research Study

For children capable of providing assent:

I have explained this study and the procedures involved to _____ in terms he/she could understand and that he/she freely assented to take part in this study.

_____
Person Obtaining Assent

_____ _____
Signature of Person Obtaining Assent Date

This study has been explained to me and I agree to take part.

_____ _____
Signature of Subject (optional) Date

For children unable to assent:

I certify that _____ was not capable of understanding the procedures involved in the study sufficiently to assent to study participation.

_____
Person Responsible for Obtaining Assent

_____ _____
Signature of Person Responsible Date