Children's Hospital of Philadelphia

Verbal Consent 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 16, 2020

Consent Name: Clinician Verbal Consent

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

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.

Why are you being asked to take part in this study?

You are being asked to take part in this research study because you are a physician or hospital administrator working at a children's hospital that is participating in a research study on improving antibiotic use at hospital discharge.

What is the purpose of this research study?

We are conducting a research study to learn more about the way antibiotics are prescribed when patients are discharged from the hospital.

How many people will take part?

Approximately 120 clinicians will take part in the study, including approximately 30 clinicians from your hospital.

What are the study procedures?

All study procedures will be conducted by Dr. Julia Szymczak and her team from the University of Pennsylvania during a 2 week visit to your hospital.

You may opt to participate in one, two or all three of the following procedures:

Semi-structured interview: Interviews will be conducted asking a series of questions about your work experiences, your opinion on how decisions about antibiotics are made at hospital discharge and antibiotic stewardship. Interviews may be tape recorded. The researcher will ask your permission to digitially record the interview before the start of the interview.

If you opt to take part in the interview, your interview participation will last about 45 minutes.

Ethnographic observation: Dr. Szymczak wil observe clinicians as they go about their work each day focusing on prescribing decisions surrounding hospital discharges.

If you opt to participate in the ethnographic observation, your observation participation will last about 8 hours.

Surveys: You will complete electronic surveys assessing knowledge, attitudes and practices surrounding discharge prescribing plus questions about your hospital's readiness to make changes.

If you opt to participate in the surveys, your survey participation will last about 15 mintues.

What are the risks of this study?

Overall, this study entails minimal risk to participants. There are no physical risks but you might experience momentary embarrassment or discomfort from the surveys, interviews, or observation. For surveys/interviews, you do not have to answer any questions that make you too uncomfortable.

Risks associated with breach of confidentiality:

As with any study involving collection of data, there is the possibility your confidentiality information will be shared with others. Every precaution will be taken to secure your personal information to ensure confidentiality. We will not gather any protected health information and the researchers will never record names in fieldnotes or audiotapes of interviews. The only identifying information collected will be your job title and the number of years employed. We will assign you a de-identified code that will be used in all notes, transcripts, presentations and publications. Inadvertent names that are captured via audio will be redacted.

The investigator will immediately cease observation, note-taking, or conducting an interview at the request of a participant.

As a CHOP employee, your decision to participate will not be shared with your supervisor and will not have any effect on your performance evaluation or employment status.

Are there any benefits to taking part in this study?

While there will be no direct benefit to you from taking part in this study, the knowledge gained from this study may help inform the design of policies meant to improve the quality, safety, efficiency and cost-effectiveness of hospital care.

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

By participating in the semi-structured interviews, ethnographic observations, and/or completion of surveys, you are indicating that you have had your questions answered, and you agree to take part in this research study.

Participation in this study is voluntary. If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits ot which you are otherwise entitled. You can stop your participation at any time.

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. We will not record your name or other personal identifying information beyond your job title and the number of years you have been employed at your position. We will assign you a de-identified code that will be used in all notes, transcripts, presentations and publications.

By law, CHOP is required to protect your private information. The investigator and staff involved with the study will keep your private information collected for the study strictly confidential and will not be shared with supervisors.

What will happen with my audio recordings?

All data files will be stored on a password-protected computer in a locked office at the University of Pennsylvania. All audio files of interviews will be destroyed as soon as they are transcribed.

Financial Information

Will you be paid for taking part in this study?

No. There are no costs or payments to participate in the study.

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, call the principal investigator, Dr. Jeffrey Gerber, at 267-426-8775.

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 and specimens (if applicable) 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

Documentation of Verbal Consent to Take Part in this Research Study

_____
Name of Subject

The research study and consent form were explained to:

_____
Person Providing Consent

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

_____ _____
Person Obtaining Consent Signature of Person Obtaining Consent

_____
Date