Title: Improving Family Meetings in the Pediatric Cardiac Intensive Care Unit

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The Children's Hospital of Philadelphia®

Informed Consent Form and HIPAA Authorization

Study Title:	**Communication Skills Training for Interprofessional Teams in Pediatric Cardiac Intensive Care Unit**
Version Date:	December 21, 2021
Consent Name:	Patient and Parent Survey and Interview Consent

Principal Investigator: Jennifer Walter, MD PhD MS Telephone: (267)426-7466

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.

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.

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 the parent participants and "your child" refers to child participants.

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

You are being asked to take part in this research study because your child has been in the cardiac intensive care unit (CICU) for at least 7 days and may stay longer or you have already been admitted for14 days and you communicate with the clinical team about your child's care.

What is the purpose of this research study?

The purpose of this study is to learn more about the way that clinician teams communicate with families in the CICU in the context of planned family meetings. This study hopes to improve communication and teamwork for clinician teams in the CICU. We plan to train the clinical teams in communication skills and want parental input about challenges you have talking with the clinical team. We hope that this study will improve how families and clinical teams talk about what is most important to you and your child when making decisions about their care. We also hope parents feel more prepared for planned family meetings and have the information they need after the meeting.

How many people will take part?

About 130 parents or guardians of children in the CICU at CHOP will take part.

What is involved in the study?

If you agree to take part in the study, we will audio or video record a planned family meeting that you have with the team to learn about the communication by the team with you. After the meeting, we will ask you to complete an online survey to learn about your experiences

communicating with the clinical team or in family meetings, and your experience with the family meeting process. For the parents who choose to use an online preparation worksheet for the family meeting, we will view what you enter into the form. You will also be asked to participate in a 20 minute interview about the usefulness of preparing for the family meeting and the written summary of the meeting if you received them.

How long will you be in this study?

If you agree to take part, you will be in the study from the time that you consent until you have completed the survey and the interview, which may be from 2 days until approximately 2 months.

What are the study procedures?

The study involves the following tests and procedures.

Tracking of the Family Meeting Preparation Worksheet:

We will record if and how you utilize the online Family Meeting Preparation Worksheet

Recording of the Family Meeting:

We will audio or video record the planned family meeting in the Cardiac Intensive Care Unit

Survey: The research team member will provide you with a survey that consists of several questions to be completed on-line. The questions will ask about the following:

- Your preferences for making decisions about your child's care
- How you feel about communication with the clinical team
- How satisfied you are with your child's care and the decision-making process
- How trusting you are of the clinical team
- How you would describe your emotional well-being
- How you felt about and if you used the Family Meeting PreparationWorksheet prior to the family meeting
- Your response to the written summary of the family meeting if you received one.
- Some demographic information

Interview: You may participate in a short interview to learn about your perceptions of the preparation process for the family meeting and the written summary received after the meeting.

Medical Record Review:

Your child's medical chart will be reviewed to get information about their time in the CICU and hospital.

Visit Schedule

The table below provides a brief description of the purpose and duration of the study visit.

Visit	Purpose	Main Procedures	Duration
Visit 1, Day 1	Enrollment	Informed Consent Review Inclusion/Exclusion Criteria	20 minutes
Visit 2, Day 1-10	Data Collection	Recording of the Family Meeting	30-60 minutes
Visit 3, Day 1-60	Data Collection	Survey	20 minutes
Visit 4, Day 2-60	Data Collection	Interview	20 minutes

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. If you have any questions about any of the possible risks listed below, you should talk to Dr. Walter or your regular doctor.

While in this study, you or your child's personal health information may not be kept confidential. You could also be at risk of a breach of confidentiality of the sensitive information contained in the study procedures. You can stop participation in the study at any time if you feel that your or your child's personal information will not be kept safe.

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 improve their teamwork and communication skills. This study may also inform clinicians on how to best prepare families for family meetings with the team.

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. 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 you change your mind later, there will be no changes to your child's medical care at CHOP.

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 the study is stopped or if you cannot meet all the requirements of the study.

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

As part of this research, health information about your child will be collected. This will include information from medical records related to your child's CICU stay. Sensitive information will also be collected from the study procedures as part of this research. 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.

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.

The identifiable information from this study will be destroyed after the study is completed and published. 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.

Certificates of Confidentiality (CoC)

A Certificate of Confidentiality (CoC) issued by the NIH covers this research. A CoC helps protect your identifiable information.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- No one can be forced to share your identifiable information for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

If you consent, your information could be shared for:

- Other future scientific research;

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The National Heart, Lung, And Blood Institute of the National Institutes of Health may need information to assess this project.
- You can still share information about yourself. You can also freely discuss your involvement in this research.
- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

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 tell the investigator in writing.

Dr. Jennifer Walter
The Children's Hospital of Philadelphia
34th Street and Civic Center Blvd.
Philadelphia, PA 19104

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 will continue to be billed to you or your insurance.

Will there be any additional costs?

There will be no extra costs to you for taking part in this study.

Will you be paid for taking part in this study?

You will be given a gift card for $20 for your time and effort in the study. The payment of $20 will be given to you upon confirmation of you finishing the study procedures. If you receive payment using a bankcard, the bank will have access to identifiable information. The bank will not have access to any medical information.

Who is funding this research study?

The National Heart, Lung, And Blood Institute of the National Institutes of Health under Award Number K23HL141700 is providing funding for this study.

Please ask Dr. Walter if you have any questions about how this study is funded.

What if you have questions about the study?

If you have questions about the study, call the study doctor, Dr. Jennifer Walter at (267)-426-7466. 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.

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 and to allow your child to take part in this research study, and you are legally authorized to consent to your child's participation. You are also agreeing to let CHOP use and share the health information that will be collected for this study and your survey information, as explained above. If you don't agree to the collection, use and sharing of health information and your survey information, you and your child cannot participate in this study.

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's participation

Name of Parent	
Signature of Parent	Date

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

Name of Subject

The research study and consent form was explained to:

Person Providing Consent

Relation to subject:
☐ Parent ☐ Legal Guardian

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

They confirmed that they were legally authorized to consent to their child's participation.

They agreed to let CHOP use and share their child's health information.

Person Obtaining Consent

Signature of Person Obtaining Consent

Date