Columbia University Medical Center

Consent Form to Participate in a Research Study

1. Title of research study and general information

Study title: Informative resources used by families of pediatric patients diagnosed with complex cardiac disease

Study number: IRB-AAAT7433

Participation duration: 5-10 minutes
Anticipated number of research participants at this site: 200
Sponsor/Supporter: None

2. Researchers' contact information

Principal Investigator: Dr. Usha Krishnan
Phone Number: 212-305-4436
Co-Investigator/Study Coordinator: Francisca Chou
Phone Number: 214-491-0614

3. What information is on this form?

We are asking you to take part in a research study.

This form explains why we are doing this study and what you will be asked to do if you choose to be in this study. It also describes the way we (Researchers) would like to use and share information about you. Please take the time to read this form. We will talk to you about taking part in this research study. You should ask us any questions you have about this form and about this research study. You do not have to participate if you do not want to.

This consent form is written to address a research subject. If consent will be obtained from the parent (or legal guardian) of a minor, the words "you" and "your" should be read as ("your child" or "the research subject").

4. Why is this study being done?

We are doing this research study to learn more about the types of informative resources families use to learn about complex heart conditions.

We also want to find out if families from different backgrounds differ in the types of resources used to learn about complex heart conditions.

5. What will I be asked to do if I choose to be in this study?

We will ask you to complete one survey and provide your contact information.

This study will last until March 31st, 2022

6. Are there any risks?

We do not think that there are any risks to taking part in this study. You can choose to skip questions on the survey if they make you uncomfortable.

Loss of confidentiality
A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy. Their plans for keeping your information private are described in section 8 of this consent form.

7. Are there any benefits?

You will not benefit from taking part in this study, but your participation may help people who have complex heart conditions in the future.

8. What about my privacy?

Every effort will be made to keep your personal information confidential. However, we cannot guarantee total privacy.

Your survey will be assigned a code number. Your name or any other information that could identify you will not be collected as part of the survey. Your name will not be linked to the survey and will not be included in any publications. The research file containing your name and contact information will be kept in a password protected database. Only the principal investigator and the study staff will be able to see this file.

The following people and/or agencies will be able to look at, copy, use and share your research information:
- The investigator, Columbia University Medical Center study staff and other professionals who may be evaluating the study
- Authorities from Columbia University, including the Institutional Review Board ('IRB') An IRB is a committee organized to protect the rights and welfare of people involved in research.
- The Federal Office of Human Research Protections ('OHRP')

Information collected as part of this research, even if identifiers are removed, will not be used or distributed for future studies.

9. Will I get paid or be given anything to take part in this study?

You will not receive any payment or other reward for taking part in this study.

10. Will I incur costs if I take part in this study?

There will be no costs to you for being in this study.

11. What are my rights if I take part in this study?

Taking part in this study is your choice. You can decide not to take part in or stop being in the study at any time for any reason. Your choice will not change the treatment you receive from doctors and staff at Columbia University Medical Center.

If you no longer want to participate in this research, you must notify the principal Investigator, Dr. Usha Krishnan at 212-305-4436.

12. Who can I call if I have questions?

You may call Francisca Chou at 214-491-0614 if you have any questions or concerns about this research study.

If you have any questions about your rights as a research participant, or if you have a concern about this study, you may contact the Institutional Review Board listed below.

Institutional Review Board
Columbia University Medical Center
154 Haven Avenue, 1st Floor
New York, NY 10032
Telephone: (212) 305-5883
irboffice@columbia.edu

13. Statement of consent and signatures

Statement of consent

I have read this consent form. The research study has been explained to me. I agree to be in the research study described above.

A copy of this consent form will be provided to me after I sign it. Another copy will be placed in my medical record.

By signing this consent form, I have not given up any of the legal rights that I would have if I were not a participant in the study.

Signatures

_____

Research Participant Date

_____

Print Name of Research Participant

_____

Parent/Guardian Date

_____

Print name of Parent/Legal Guardian

_____

Person Obtaining Consent Date

_____

Print Name of Person Obtaining Consent