

Columbia University Medical Center
Assent Form to Participate in a Research
Minor (Ages 12-17)

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, MD

Phone Number: 212-305-4436

Co-Investigator/Study Coordinator: Francisca Chou

Phone Number: 214-491-0614

3. Why are we interested in talking with you?

We are asking you to take part in this research because you have a heart condition.

Before agreeing to participate in this study, it is important that you read this form and talk with the research staff. You should only take part in this study if you want to. This form will explain why we are doing the research and what will happen to you if you are in this research study. We would like to discuss the study and review this form with you. You can ask questions at any time before, during or after our discussion. You will also have time to read this form and ask any questions about the research study. At the end, we will ask you to sign this form if you agree to participate.

It is okay to ask questions about what we are telling you. If you do not understand something, just ask us. We want you to ask any time you think of a question.

4. What is this research study about?

In this research study, we want to learn more about the types of informative resources families use to learn about complex heart conditions.

There will be about 200 participants in this study.

5. What will happen if you agree to be in the study?

The following will be asked of you, if you decide to be in this research study:

- We will ask you to answer some questions
- Answering the questions will take a few minutes while you wait for your testing

6. Are there any consequences if you participate in this study?

There is a chance that during the study you could feel uncomfortable, afraid, lonely, or hurt. We will help you with these feelings and you can **stop** at any time if you want. If you participate in the study, you could experience any of the following:

- You may feel embarrassed/uncomfortable by the questions we ask

7. Will you benefit from being in this study?

You will not benefit directly from this study. We hope to learn how to improve communication with children referred for suspected heart conditions at the clinic in the future.

8. What if you have questions?

You may ask questions at any time. You can ask now or later. You may talk to the researcher or someone else. If you have any questions about this study, you can contact Francisca Chou at 214-491-0614 (email flc2112@cumc.columbia.edu) or Dr. Usha Krishnan at 212-205-4436 (email usk1@cumc.columbia.edu).

If you have any questions about your rights when you are in a research study, you may contact the Institutional Review Board my mail, telephone, or email at:

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

An Institutional Review Board is a committee organized to protect the rights and welfare of human subjects involved in research.

9. What about your privacy?

To protect you, the information collected in this study will not be shared with anyone unless required by law.

The researchers in this study will need to talk about you and the study with your parent/guardian and with other researchers but will not talk about you with anyone else except the people working on the study. If the researcher(s) need(s) to talk to anyone else about you, he/she/they will ask you and your parent/guardian if it is okay to do so.

10. What will it cost you to be in this study?

There is no cost to you or your parents for being in this research study. You will not get paid to participate in this study.

11. Do you have to be in this study?

No, you do not have to be in this study. We are asking you if you would like to be in the study but if you say no, no one will be upset with you. You can also say yes now and if you change your mind later, you can quit the study at any time.

Please talk this over with you parents/guardians before you decide whether or not to participate. Even though your parents/guardians have said it is all right with them if you want to be in the study, you can still say **no**. If you do agree to be in the study but later decide you would rather not be in the study, you may stop your participation at any time. Your decision will not affect your care or that of your parents or family members in any way.

If you sign this paper, it means that you want to be in this study. **If you do not want to be in the study, do not sign this paper.**

Signatures

Signature of Minor

Date

Print Name of Minor

Signature of Person Obtaining Assent

Date

Print Name of Person Obtaining Assent