

RESEARCH ASSENT FORM

Title of Research Study:

Atrioventricular Septal Defect – A Congenital Heart Surgeons’ Society Inception Cohort Study

Investigators:

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Please address all questions to:

CHSS Data Center	Toll Free Line	1-866-477-2477
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Why are we doing this study?

We hope you can help us find out more about something called atrioventricular septal defect (AVSD). This is a heart disease that you were born with. Some children have different kinds of this heart disease than other ones. We want to find out how to best care for them.

What will happen during the study?

During the study we will collect information from your health records and enter it in a database with information from other children who have a similar condition. There will be no extra tests. Once a year your parent and you will be asked to answer short questionnaires to see how you are doing. When you become an adult we will ask you directly.

Are there bad things about the study?

This study is safe for you. There are no bad things about the study.

Are there good things about the study?

You will not receive any gifts for helping us with this study. However, your help will help us to improve the care of other kids with the same condition.

Who will know what I did in the study?

We can't tell anybody about this study except for the research team, but you can tell anyone you want. Your name will not be given to anyone outside of the research team. If we feel your health is in danger, we may have to tell your doctor about how you did in the study.

Certain people may look through your medical charts. A research student or staff may go through your chart to get information about how your health has been. The Research Ethics Board may also look at the information from this study to make sure that everything about the study is going OK.

Can I decide if I want to be in the study?

Nobody will be angry or upset if you do not want to be in the study. We are talking about the study with your parent and you should talk to your parent about it. Ask your parent questions if you do not understand what you have heard or read. Your parent will help you to understand. The doctors and researchers will also answer any questions you may have.

If you and your parent do not want to be part of this study, that's alright. If you and your parent say yes now but change your minds, you can say no later.

Assent:

I explained this study to _____ and/or was present when
Printed Name of Child

he or she read this form. I confirm that he or she agreed, or assented, to take part in this study.

Printed Name of Subject and Age

Signature & Date

Printed Name of Person who obtained assent

Signature & Date

*Please Note: 'Parent', also includes 'Legal Guardian' (where applicable)