

**Title: Vancouver Pediatric Palpitation Score**

**Participant Information and Adolescent  
Assent Form for Individuals 14-18 years old**

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**EMERGENCY TELEPHONE NUMBER (24 hours/day):** Dr. Sanatani or the cardiologist-on-call at B.C. Children's Hospital can be reached at 604-875-2161.

**INVITATION**

I am being invited to take part in this research study because I have experienced palpitations (where my heart beat feels strange, fast or very strong). Palpitations can happen for lots of reasons, for example if the person is sick or worried, but sometimes they are because of a problem with their heartbeat, called an arrhythmia. It is important to know the cause of palpitations because that is how doctors know which treatment to use.

We want to create a scoring system to help doctors try to work out if palpitations are due to a problem with the patient's heart, before they have lots of tests done.

No one will make me be part of the study. Even if I agree now to be part of the study, I can change my mind later. No one will be upset with me if I choose not to be part of this study.

I will read this form so that I will understand the study and if I wish to participate I will be asked to write my name on this form. My parents/legal guardians will be asked to write their name on a different form, which I will also write my name on.

### **WHO IS DOING THE STUDY?**

Dr. Sanatani, from BC Children's Hospital is doing this study. He, or his research team, will answer my questions about this study. I can also call them at 604-875-2345 ext. 7955.

### **WHY ARE WE DOING THIS STUDY?**

Lots of children go to the hospital because they have palpitations. Palpitations can happen for lots of reasons, for example if the person is ill or worried, but sometimes they are because of a problem with their heartbeat, called an arrhythmia. It is usually difficult to find out quickly why the person has palpitations, so lots of children have to visit a cardiologist for tests. It is important to know the cause of palpitations because that is how doctors know which treatment to use.

We want to make it easier for doctors to find out why someone is having palpitations without doing tests. We will collect information about lots of children with palpitations and try to find things that children with an arrhythmia have in common. We will put these together to create a score. The score will award points for certain features, and the sum of the points will then be used to predict the chance that the patient has an abnormal heart rhythm.

### **WHAT WILL HAPPEN IN THIS STUDY?**

If I want to be in this study, I will not have to do anything different to the normal things that doctors do for children with palpitations. Information about me will be put into a database. Information like my name and birthday will not be written down in the database, so no one will know it is about me. Information about lots of other children with palpitations will be put in the database too. We will look at all of the information together to try to find things that children with arrhythmia have in common.

### **CAN ANYTHING BAD HAPPEN TO ME?**

No. There is no change from normal clinical practice in this study; so nothing bad can happen to me, beyond the risks associated with my normal clinical care.

We will try our hardest to keep your medical information private. Data will be entered into a secure database and only study personnel will have access to this data. Your name and other identifying information will be kept in a very secure location under the control of the principal investigator or selected members of the research team.

### **CAN ANYTHING GOOD HAPPEN TO ME?**

No; but we hope the things we learn from the study will help other children with palpitations in the future.

### **DO I HAVE TO BE IN THIS STUDY?**

I do not have to be in this study. No one will be upset with me if I don't want to do this. If I don't want to be in this study, I just have to tell the research staff. I can say yes now and change my mind later. It is up to me. It will not make any difference to my health care if I decide to say no to the study.

### **CAN I LEAVE THE STUDY LATER?**

If I don't want to be in the study anymore I can leave without giving a reason. My healthcare will not be affected in anyway. Data collection would stop, but any data collected up to that date will be included in the database. This is to make sure the study is still good. If I wish to leave the study, I may call Dr. Sanatani or the study coordinator at 604-875-2345 ext. 7955 or I can also send Dr. Sanatani a letter (at the address listed at the top of this form), asking to be removed from the study but this is not required.

### **CAN I BE ASKED TO LEAVE THE STUDY?**

The study doctor may decide to stop the study at any time. He or she may also decide to withdraw me from the study at any time. My healthcare will not be affected in anyway.

### **WHO WILL KNOW I AM IN THE STUDY?**

My doctors and the people involved in the study will know I am in it. When the study is finished, the doctors will write a report about what is learned. This report will not say my name or that I was in the study. My parents/legal guardians and I do not have to tell anyone I am in the study if we don't want to.

### **DO MY PARENTS/LEGAL GUARDIANS KNOW ABOUT THIS?**

My parents/legal guardians know about this project, and they agree that I can be in it. I will talk this over with them before I decide. I do not have to be in the study even if my parents/legal guardians want me to be.

### **WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT MY RIGHTS AND/OR EXPERIENCES AS A PARTICIPANT DURING THE STUDY?**

If I have any concerns or complaints about my rights as a research participant and/or my experiences while participating in this study, I can contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at [RSIL@ors.ubc.ca](mailto:RSIL@ors.ubc.ca) or by phone at 604-822-8598 (Toll Free: 1-877-822-8598). I should reference the study number (H19-01638) when contacting the Complaint Line so the staff can better assist me.

## HOW DO I DECIDE?

I have as much time as I want to decide to be part of the study. I have also been asked to discuss my decision with my parents/legal guardians before I make a decision.

If I **do not** want to be part of this study I will tell the study doctor or his team or my parents. No one will be upset with me if I don't take part in the study.

If I **do** want to be part of this study I will print my name and write my name and date on the lines below.

I will receive a signed and dated copy of this form to take home.

Name \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_