Title: Vancouver Pediatric Palpitation Score

Participant Information and Consent Form

Principal Investigator: Dr. Shubhayan Sanatani, MD
Head, Division of Cardiology
Children's Heart Centre
BC Children's Hospital
Professor, Department of Pediatrics
University of British Columbia
604 875 3619
ssanatani@cw.bc.ca

Co-Investigator: Dr. Sakethram Saravu Vijayashankar, MD
Children's Heart Centre
BC Children's hospital
University of British Columbia
sakethram.vijayashan@cw.bc.ca

Coordinator: Dr. Sonia Franciosi, PhD
Research Associate, Division of Cardiology
Pediatric Heart Rhythm Research
Children's Heart Centre
Phone: 604-875-2345 Ext. 7955
Sonia.franciosi@cw.bc.ca

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.

Note: If you are a parent or legal guardian of a child who may take part in this study, permission from you and the assent (agreement) of your child is required. When we say "you" or "your" in this consent form, we mean you and/or your child; "we" means the doctors and other research staff.

INVITATION

You are being invited to take part in this research study because your child has experienced palpitations (irregular, rapid or strong pulsations in the chest). Palpitations can be caused by a variety of conditions and are broadly divided into those which are accompanied by a normal heart rhythm and those which are accompanied by an abnormal heart rhythm, or arrhythmia.

The aim of this study is to develop a scoring system based on a person's clinical history that is able to predict whether the palpitations are due to an abnormal heart rhythm or not.

YOUR PARTICIPATION IS VOLUNTARY

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences.

Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study, why the research is being done, what will happen to you during the study and the possible benefits, risks and discomforts.

When you participate in a research study, the main goal is to learn things to help other patients in the future. The researchers have a duty of care to all participants. Please take time to read the following information carefully and to discuss it with your family and friends before you decide.

If you wish to participate in this study, you should write your name and sign at the end of this form. Participants aged 18 and under must assent to taking part and their parent/legal guardian must provide consent.

WHO IS CONDUCTING THE STUDY?

Dr. Sanatani, the principal investigator, is a specialist in heart rhythm disorders in children and is conducting the study from BC Children's Hospital in Vancouver, BC.

For any questions I may have about the study, I can also call the study coordinator at 604-875-2345 ext. 7955

WHY ARE WE DOING THIS STUDY?

Heart palpitations are a common reason for children to attend the emergency room. There are a range of possible causes for palpitations, one of which is an abnormal heart rhythm, which requires specific treatment. It is often difficult to initially diagnose an abnormal heart rhythm, leading to a high number of referrals to cardiology for further investigation. This study aims to create a predictive score, based on clinical features and history, which will allow any physician to more easily identify patients with an abnormal heart rhythm, fast track cardiology investigations and initiate appropriate treatment earlier. 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.

We will collect information from patients with palpitations, including whether or not the cause of their palpitations is related to an abnormal heart rhythm (which will be established after routine investigations). We will try to find factors which are more common in people with an abnormal heart rhythm and put these together to create a score.

WHO CAN PARTICIPATE IN THIS STUDY?

You are able to participate in the study if you:

- Are a child between the ages of 6 to 18 years with a normal cardiac physical exam and ECG
- Have experienced recent and ongoing palpitations in the last 6 months
- Are able to describe your symptoms on the questionnaire
- Are able and willing to provide assent for the study and have a parent or guardian who is willing and able to provide consent.

WHO SHOULD NOT PARTICIPATE IN THIS STUDY?

You should not participate in the study if:

- You have any cardiac diagnosis prior to completing the questionnnaire
- You have an abnormal echocardiogram, except some small structural changes to your heart which do not increase the risk of an abnormal heart rhythm at the time of questionnaire
- You have a family history of sudden unexpected death and/or inherited arrhythmia
- You are unable to provide assent/consent to participate in this study

WHAT DOES THE STUDY INVOLVE?

If you decide to take part in this study, you will not be required to do anything in addition to the standard medical care for someone who is being investigated for palpitations. Once you have signed this consent form, your clinical history and results from clinical monitoring (Holter monitor, event monitor or Loop Recorder), will be de-identified (ie your name, date of birth, hospital number etc will be removed) and recorded in a database. Your data will be analysed along with data from other people with palpitations to try to work out if there are certain factors which are more common in people with an abnormal heart rhythm. If any are found they will be used to create a scoring system to make it easier for all physicians to determine if palpitations are being caused by an abnormal heart rhythm or not.

WHAT ARE THE POSSIBLE HARMS AND DISCOMFORTS?

The study does not require anything in addition to standard clinical care therefore there are no additional harms or discomforts that may occur due to this study.

There is possible risk of loss of confidentiality. Every effort will be made to keep your information confidential but this cannot be guaranteed.

WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING?

There will be no direct benefit to you participating in this study; however the knowledge gained will be used to help other children with palpitations in the future.

WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?

If you wish to withdraw from the study, data collection would cease. Any data collected up to the date of withdrawal will be included in the database. This is to reduce study bias and ensure the scientific validity of the research. You may withdraw from this study at any time without giving reasons. If you wish to leave the study, you may call Dr. Sanatani or the study coordinator at 604-875-2345 ext. 7955 or

you 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. This will in no way affect your standard of care.

CAN I BE ASKED TO LEAVE THE STUDY?

If you are not complying with the requirements of the study, the study doctor may withdraw you from the study. On receiving new information, the study doctor might consider it to be in your best interests to withdraw you from the study without your consent if they judge that it would be better for your health. This will in no way affect your standard of care.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

Every effort will be made to keep your personal medical information confidential. 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. Study data will be entered into an encrypted, password-protected computer and the database will also be password-protected. The de-identified data will be kept indefinitely to allow continuing analyses of the study results, maximizing what can be learned from the study. The link to your personal information will be kept for five years after completion of the study, after which time, the link will be destroyed and the data will become anonymous.

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY DURING MY PARTICIPATION?

If you have any questions or desire further information about this study before or during participation, you can contact Dr. Shubhayan Sanatani or the research coordinator at 604-875-2345 ext. 7955.

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

CONSENT TO PARTICIPATE

My signature on this form means:

- I have read and understood the participant information and consent form.
- I have had sufficient time to consider the information provided and to ask for advice if necessary.
- I have had the opportunity to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the result will only be used for scientific objectives.
- I understand that my participation in this study is voluntary and that I am completely free to refuse to participate without changing in any way the quality of care that I receive.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I understand that there is no guarantee that this study will provide any benefits to me.
- I have read this form and I freely consent to participate in this study.
- I have been told that I will receive a dated and signed copy of this form.

The parent(s)/legal guardian(s) and the Investigator are satisfied that the information contained in this consent form was explained to the child to the extent that he/she is able to understand it, that all questions have been answered, and that the child assents to participating in the research.

As a Parent/Legal Guardian of a child participating in this study

☐ I consent to my child's participation in this study

SIGNATURES

Printed name of Participant	Signature	Date
Printed name of participant's parent/legal guardian	Signature	Date
Printed name of Investigator/Designate	Signature	Date

Was the participant assisted during the consent process?

☐Yes ☐No *If yes, please check the relevant box and complete the signature space below:*

☐ The consent form was read to the participant, and the person signing below attests that the study was accurately explained to, and apparently understood by, the participant (check if participant is unable to read).

☐ The consent form was translated, and the person signing below attests that the study was accurately explained to, and apparently understood by, the participant.

Signature	Printed Name	Date

Language Consent Translated to: _____