CHILDREN'S & WOMEN'S HEALTH CENTRE OF BRITISH COLUMBIA

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SUBJECT INFORMATION AND CONSENT FORM

Title of Study: Do I Wheeze? Utilizing respiratory sounds to develop an algorithm for detecting wheeze

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When we say "you" in this consent form, we mean you or your child.
When we say "we" in this consent form, we mean the doctors and researchers involved in this study. They are listed at the top of this page.

1. INTRODUCTION

You are invited to participate in this study because you have been admitted to hospital and are displaying clinical signs of wheeze (continuous whistling sounds produced during breathing, caused by some lung problems) or have unobstructed (normal) breathing. We are taking short audio recordings to develop a step by step procedure for automatically distinguishing children with wheeze from children without wheeze.

2. YOUR PARTICIPATION IS VOLUNTARY

Your participation is entirely voluntary, so it is up to you to decide whether or not to participate. 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.

If you do decide to participate, you will be asked to sign this form. Even after you have done this, you are free to withdraw from the study at any time, and you do not have to give any reasons for your decision.

If you choose not to be involved or withdraw from the study, you do not have to tell us why. The medical care that you will be receiving will not be any different or less than the care you would normally receive. Please take time to read this information and ask any questions that may help you to understand the study before you decide whether or not to be in the study.

3. BACKGROUND

Two million children under the age of five, the majority in the developing world**,** die from pneumonia each year. We are developing mobile phone based technologies to improve the diagnosis and treatment of pneumonia.

There is a significant challenge in distinguishing between children with wheezy diseases (such as asthma) and pneumonia as the symptoms used for diagnosis are similar. Preliminary results from a study, by Dr. Michael Seear and his team at BCCH, in a large group of children in India indicate that 40% of children with clinical signs of pneumonia did not have pneumonia but had wheezing diseases.

4. WHY IS THIS STUDY BEING DONE?

The treatments for pneumonia and wheeze are very different. The ability to accurately detect wheeze in children will allow us to reduce the use of antibiotics in children who do not have pneumonia. We will use audio (sound) recordings from a child's chest to develop an automatic method for differentiating children with and without wheeze.

5. WHO CAN PARTICIPATE IN THE STUDY?
In order to participate in the study, you must be under the age of 17 and fall into either one of two categories: 1) children with unobstructed breathing, or 2) children who present with clinical signs of wheeze.

6. WHAT DOES THE STUDY INVOLVE?
The study is taking place in the emergency department, respiratory clinic, intensive care unit, wards and the surgical day care unit at BCCH. We will recruit 100 children (50 with wheeze and 50 without wheeze).

As a subject in this study, audio recordings will be made using an electronic stethoscope applied to 8 locations on your front and back. You will be asked to breathe normally for one minute and then to take 5 big slow breaths. We will do more than one location at a time to minimize the amount of time needed to do all the recordings. This does not hurt and is similar to when a doctor uses a stethoscope to listen your heart and lungs.

There are no changes to your medical treatment. Once we have completed all four recordings, your participation in the study is finished.

7. WHAT ARE THE POSSIBLE HARMS AND SIDE EFFECTS OF PARTICIPATING?
There are no additional harms or potential side effects in participating in this study. This is a non-invasive study in which four short audio recordings of your breathing will be taken.

8. WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?
There are no direct benefits to your participation in this study. The information we obtain from the study will be used to improve respiratory rate measurement that will be used for others in the future. There is no financial reimbursement for participation.

9. WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?
Your participation in this research is entirely voluntary. You may withdraw from this study at any time. If you decide to enter in the study and withdraw at any time in the future, there will be no penalty or loss of benefits to which you are otherwise entitled, and your future medical care will not be affected.

10. WHAT ARE MY LEGAL RIGHTS?
Signing this consent form in no way limits your legal rights against the sponsor, investigators or anyone else.

11. CAN I BE ASKED TO LEAVE THE STUDY?
The study doctor(s)/investigators may decide to discontinue the study at any time, or withdraw you from the study at any time, if they feel that it is in your best interests.

12. WHAT WILL THE STUDY COST ME?

There will be no additional financial cost to you for your participation in the study. You will not be charged for any research procedure. You will not receive any remuneration/reimbursement for participation.

13. WILL MY PARTICIPATION IN THIS STUDY BE KEPT CONFIDENTIAL?

Your confidentiality will be respected. However, research records and medical records identifying you may be inspected in the presence of the Investigator or her/his designate by UBC Children's & Women's Research Ethics Board for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a subject in this study. Only this number will be used on any research-related information collected about you during the course of this study, so that your identity (i.e. your name or any other information that could identify you) as a subject in this study will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique identifier that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected and also give you the right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor.

14. 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 your participation, you can contact Dr. Ansermino at 604-875-2711.

15. WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT MY RIGHTS AS A SUBJECT DURING THE STUDY?

If you have any concerns about your treatment rights as a research subject, please contact the Research Subject Information Line at the University of British Columbia Office of Research Services at 604-822-8598 (Toll Free Number 1-877-822-8598) or if long distance, email to RSIL@ors.ubc.ca.

17. CONSENT TO PARTICIPATE

My signature on this consent form means:

- I have read and understood the subject 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 results 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 or to withdraw from this study at any time 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.

The parent(s)/guardian(s)/substitute decision-maker (legally authorized representative) and the investigator are satisfied that the information contained in this consent form was explained to the child/subject to the extent that he/she is able to understand it, that all questions have been answered, and that the child/subject assents to participating in the research.

I will receive a signed copy of this consent form for my own records.

I consent to participate in this study.

Subject's Signature	Printed Name	Date
Parent/Guardian Signature	Printed Name	Date
Signature of Person Obtaining Consent	Printed Name	Study Role Date