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

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SUBJECT INFORMATION AND CONSENT FORM

Title of Study:

***Panda*:**
Evaluation of a smartphone-based perioperative pain assessment tool

Principal Investigator :
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Michelle Misse, Post-Anesthetic Care Unit, Tel 604-875-2000 x. 5647

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 may be required. When we say "you" or "your" in this consent form, we mean you and/or your child; "we" means the doctors and other staff.

INVITATION

You are invited to participate in this study because you will spend some time in the Post-Anesthetic Care Unit (PACU), recovering from your surgery. Our research is studying the *Panda*, a smartphone application (or 'app'), which is designed to collect scores which represent a child's pain following surgery.

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 to the medical care, education, or other services to which you are entitled and presently receiving.

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 wish to participate in this study, you will be asked to sign this form.

Please take time to read this information and ask any questions that may help you understand the study before you decide whether to participate.

WHO IS CONDUCTING THE STUDY?

The study is being conducted by the principal investigator, Dr. Gillian Lauder, who is a staff pediatric anesthesiologist and Director of the Acute Pain Service (APS) at BC Children's Hospital (BCCH). Other researchers involved in the study are Dr. Mark Ansermino (a pediatric anesthesiologist), Nicholas West and Aryannah Umedaly (researchers in the Department of Anesthesia at BCCH) and Michelle Misse (Clinical Nurse Coordinator in the PACU at BCCH).

No investigator is receiving financial compensation from any outside funding agency for conducting or being involved with the study. There is no possibility of benefit to the investigators from commercialisation of any research findings.

BACKGROUND

Many children and adolescents suffer some degree of pain following surgery. After your surgery today, you will spend some time in the Post-Anesthetic Care Unit (PACU), which is staffed by a dedicated nursing team. Your PACU nurse will assess whether you are experiencing any pain and, if you are, how bad it is. This will help determine what medication you may need.

The *Panda* is a smartphone application (or 'app'), which has been designed to collect scores which represent a child's pain following surgery. Traditional tools for assessing your pain include asking you to rate it on a scale from 1 to 10, asking you to move a slider along a coloured scale or asking you to point to one of a series of faces on a piece of card. The *Panda* app is based on the same methods, but presents them on the smartphone's screen.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to ensure that the *Panda* app can be used by children after surgery and that it obtains the same scores as the traditional tools.

WHO CAN PARTICIPATE IN THE STUDY?

In order to participate in the study, you must be between 4 and 18 years old, in general good health, and scheduled for elective day surgery.

WHO SHOULD NOT PARTICIPATE IN THE STUDY?

You should not participate in this study if you have a psychiatric diagnosis, developmental delay or brain injury, significant visual impairment or psychomotor dysfunction. If you have any questions about your eligibility, please speak with a member of our research team or your anesthesiologist.

WHAT DOES THE STUDY INVOLVE?

This study is taking place in the PACU at BCCH. We will recruit 200 children.

There are no extra medications required for this study. If you agree to take part, the study procedures will include the following:

- you will be asked to rate your pain using both the *Panda* and a traditional tool (which is used first will be decided randomly, as with the flip of a coin)
- you may be asked your opinion; for example, which tool you preferred using and about any problems you experienced using either tool

WHAT ARE MY RESPONSIBILITIES?
There are no additional responsibilities or requirements necessary for you to participate in this study, apart from answering questions about your pain and your opinion about which tool was easiest for you to use.

WHAT ARE THE POSSIBLE HARMS AND DISCOMFORTS?
There are no additional harms or side effects associated with this study.

WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING?
There are no additional benefits associated with participating in this study.

WHAT ARE THE ALTERNATIVES TO THE STUDY TREATMENT?
If you choose not to participate in this study or to withdraw at a later date, your care will not be affected. Your PACU nurse will use the traditional tools to assess any pain you may be experiencing.

WHAT IF NEW INFORMATION BECOMES AVAILABLE THAT MAY AFFECT MY DECISION TO PARTICIPATE?
If you choose to enter this study and new information becomes available that may affect your willingness to remain in the study, you will be advised and may withdraw if you choose to do so.

WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?
You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then later decide to withdraw, all data collected about you during your enrollment in the study will be retained for analysis.

CAN I BE ASKED TO LEAVE THE STUDY?
If you are unable to follow the requirements of the study, or for any other reason, the study doctor may withdraw you from the study and will arrange for your care to continue.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?
Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or her/his designate by representative, and the UBC C&W 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 study number 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.

AFTER THE STUDY IS FINISHED

The results of this study will be shared with other psychologists and anesthesiologists by presentations at scientific meetings and/or by publication in scientific journals at the conclusion of the study. Please check the Pediatric Anesthesia Research Team (PART) website (http://www.part.cfri.ca) for information regarding this study and for information on accessing the results.

WHAT HAPPENS IF SOMETHING GOES WRONG?

Signing this consent form in no way limits your or the subject's legal rights against the investigators or anyone else, and you do not release the study doctors or participating institutions from their legal and professional responsibilities.

WHAT WILL THE STUDY COST ME?

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

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

If you have questions or desire further information about this study, before or during your child's participation, you can contact Dr. Lauder at 604-875-2711.

WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT MY RIGHTS AS A SUBJECT?

If you have any concerns about your rights as a research subject and/or your experiences while participating in this study, contact the Research Subject Information Line in the University of British Columbia Office of Research Services by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598).

SUBJECT CONSENT TO PARTICIPATE

Title of Study:

***Panda*:**
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My signature on this consent form means:

- I have read and understood the subject information and consent form.
- I have had the opportunity to ask questions and have had satisfactory responses to my questions.
- 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 she/he 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 Name

_____
Parent/Guardian Signature Printed Name Date

_____
Signature of Person Obtaining Consent | Printed Name | Study Role | Date

If this consent process has been done in a language other than that on this written form, with the assistance of an interpreter/translator, indicate:

Language: _____

Was the subject assisted during the consent process in one of ways listed below?
☐ Yes ☐ No

If Yes, please check the relevant box and complete the signature space below:

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

☐ The person signing below acted as an interpreter/translator for the subject, during the consent process (please check if an interpreter/translator assisted during the consent process).

Person Assisting in the Consent Discussion Signature	Printed Name	Date

SUBJECT'S ASSENT TO PARTICIPATE

I have had the opportunity to read this consent form, to ask questions about my participation in this research, and to discuss my participation with my parents/guardians. All my questions have been answered. I understand that I may withdraw from this research at any time, and that this will not interfere with the availability to me of other health care. I have received a copy of this consent form. I assent to participate in this study.

_____

Signature Printed name of subject Date