



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

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SUBJECT INFORMATION AND CONSENT FORM

Title of Study: Real Time Assessment of the Intelligent Anesthesia Navigator

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You are being invited to participate in this research study because you are a staff anesthesiologist, anesthesia resident or fellow at BCCH.

BACKGROUND

Alarms produced by current monitoring systems are based on predetermined upper and lower limits. However, physiological parameters vary normally over time within these limits. Current systems result in a significant number of distracting false alarms. At the same time, alarm systems may not detect changes to a trend that occur between the upper and lower limits resulting in abnormalities that may go undetected.

Clinicians have a better appreciation of the underlying human physiology and how it changes over time, which is not taken into account in the alarm system. Yet maintaining attention, to detect the often-small changes in parameters, is difficult for the anesthesiologist – especially in very long procedures. Demands on the attention of clinicians are intensifying with the growing numbers of monitors in the operating room.

WHAT IS THE PURPOSE OF THE STUDY?

The overall purpose of this study is to contribute to the development of a decision support system for clinical anesthesiologists that integrates the steady stream of data

produced by patient monitoring systems. The objective in this study is to conduct a real time assessment of the Intelligent Anesthesia Navigator (IAN).

WHO CAN PARTICIPATE IN THE STUDY?

Staff anesthesiologists, anesthesia residents and fellows at BCCH may participate in this study.

WHO CANNOT PARTICIPATE IN THIS STUDY?

People are not staff anesthesiologists, anesthesia residents and fellows at BCCH cannot participate in this study.

WHAT DOES THE STUDY INVOLVE?

Beyond that which is required for standard patient care, you will be expected to interact with the IAN system when it alerts you with audio and/or visual cues to changes in the physiological data. You will be asked to rate each alerted event during the procedure on two different scales; a significance scale, and a usefulness scale, which will take approximately 1 minute per event. If at any time, you feel that the system is interfering with the care of your patient, you are free to stop and revert back to the standard monitoring practices. Data from the bedside monitors will also be stored on a laptop computer during the procedure.

After the procedure, you will be asked to complete a short survey for demographic purposes. There is also a Post-Study System Usability Questionnaire (PSSUQ) that will need to be completed, asking you about the general usability of the IAN system. These two tasks will take approximately 10 -15 minutes.

WHAT ARE MY RESPONSIBILITIES?

You will be responsible for standard patient care, and to interact with the IAN. We emphasize that this is a study of the IAN rather than of the patients. Most importantly, there is no modification of the treatment of any patient. You are not required to heed any advice produced by the system. You are only being asked to evaluate the system.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

It is unlikely that you will directly benefit from this study. The information gained during this study may help anesthesiologists in the future with the development of a new anesthesia monitoring system.

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. You do not have to provide any reasons for your decision. 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.

If you choose to enter the study and then decide to withdraw at a later time, all data collected in the study will be retained for analysis. By law, this data cannot be destroyed.

WHAT HAPPENS IF SOMETHING GOES WRONG?

By signing this consent form you are in no way waiving your legal rights against the sponsor, investigators, or anyone else.

WHAT WILL THE STUDY COST ME?

There will be no additional cost to you for your participation in the study.

WILL I RECEIVE ANY REIMBURSEMENT FOR PARTICIPATING?

You will not receive any compensation or reimbursement for participating in this study.

WILL MY PARTICIPATION IN THIS STUDY BE KEPT CONFIDENTIAL?

Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent to the disclosure. However, research records and medical records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of Health Canada and the UBC Research Ethics Board for the purpose of monitoring the research. However, records which identify you by name, initials or date of birth will be kept in a locked cabinet and will not be allowed to leave the Investigators' offices. Copies of relevant data, which identify you only by code number, may be required by the regulatory agencies or viewed by other collaborators or industry partners in comparing different methods to identify changes that occur in the monitoring under anesthesia. However, you will not be identified by name, initials, or date of birth as part of this study data.

The fact of your participation in this study cannot be kept strictly confidential as you will be observed in the operating room interacting with the IAN system, and possibly the research assistant(s). However, we will not provide a list of participants or non-participants to anyone not involved in running this study. In particular, we will not provide such a list to anyone who has supervisory responsibilities. In reporting results from this study, we will not identify you.

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. Mark Ansermino at 604-875-2711.

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 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.

CONSENT TO PARTICIPATE

I have read all of the above. I have had enough time to consider entry to the study. All of my questions have been answered to my satisfaction. I understand that my participation is entirely voluntary and that I may refuse to participate, or may withdraw from the study at any time.

I acknowledge having received a signed and dated copy of this consent form for my own records.

You do not waive any of your legal rights by signing this consent form.

Printed name of subject	Signature	Date
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Printed name of witness	Signature	Date
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Printed name of principal investigator/ designated representative	Signature	Date
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