



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

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## SUBJECT INFORMATION AND CONSENT FORM

### **iControl: Interface Usability Evaluation**

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#### **BACKGROUND**

You are invited to participate in this research study because you are a staff anesthesiologist or senior resident anesthesiologist (year 3-5).

Closed-loop control technology is used extensively in many fields, but has yet to make a significant impact in anesthesia. One of the main reasons for this is the natural concerns about safety of closed-loop systems in medical applications. Thus, while this form of control has proven beneficial in many contexts outside medicine, it is only once the safety has been demonstrated, and large clinical trials subsequently performed, that it will be possible to determine if closed-loop control provides a better clinical outcome than current practice in anesthesia.

The most effective interface that allows the anesthesiologist to monitor, supervise and intervene during the automated drug delivery is being investigated, and we are seeking to test whether our current prototype meets the needs of anesthesiologists. A successful implementation should allow the user to closely monitor the automated infusion of propofol and provide a simple and safe way to override control in the event of automation malfunction.

It is our intent to optimize these aspects of our prototype through this usability study. iControl is a software application that is being developed by our research team to provide closed-loop control of anesthesia.

### **WHAT IS THE PURPOSE OF THE STUDY?**

To evaluate the usability of the interface of a control prototype (iControl) in the hands of expert anesthesiologists to determine areas of improvement for the interface.

### **WHO CAN PARTICIPATE IN THE STUDY?**

Consenting anesthesiologists and anesthesia residents (years 3-5) may participate in this study.

### **WHO CANNOT PARTICIPATE IN THIS STUDY?**

Subjects that do not consent or who are unable to consent cannot participate in this study.

### **WHAT DOES THE STUDY INVOLVE?**

As a subject in this study, we ask you to perform a simulated clinical scenario to interact with iControl to examine its usability. You will be given a list of tasks to complete.

You will be given instruction on how to “think aloud” (we will audio record your speech), and an iControl Users Manual.

When the test period is completed, you will be asked to fill out a short questionnaire, for your feedback and comments on the interface. The test will be completed in less than one hour.

### **Audio Recordings**

All digital audio recordings will be kept safely on password protected computers in a locked cabinet in a locked office. Only the Investigators and designated representatives will have access to the recordings. The recordings will be given unique code numbers and no identifiable information will be used. The recordings will be stored on site for 5 years and then destroyed. There are no plans for secondary use of the audio recordings.

### **WHAT ARE YOUR RESPONSIBILITIES?**

You are responsible for interacting with the iPleth interface and “thinking aloud” to provide insight into your use of the application.

### **WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?**

The results of this study will determine the usability of iControl, including possible areas for improvement. This will lead to future versions of iControl being more widely used by clinicians.

### **WHAT HAPPENS IF YOU DECIDE TO WITHDRAW CONSENT TO PARTICIPATE?**

Your participation in this research is entirely voluntary. You may withdraw from this study at any time without providing any reasons. 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 or releasing the investigator from their legal and professional responsibilities.

**WHAT WILL THE STUDY COST?**

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

**WILL YOUR 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 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 Boards 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. 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 study. 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 TO CONTACT IF YOU HAVE QUESTIONS ABOUT THE STUDY DURING YOUR PARTICIPATION?**

If you have any questions or desire further information about this study before or during your participation, contact Dr. Mark Ansermino at 604-875-2711.

**WHO DO YOU CONTACT IF YOU HAVE ANY QUESTIONS OR CONCERNS ABOUT YOUR RIGHTS AS A SUBJECT DURING THE STUDY?**

If you have any concerns about your rights and/or experiences as a research subject, please contact the Research Subject Information Line at the University of British Columbia Office 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.

I do not waive any of my legal rights by signing this consent form.

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