Participant Information and Consent Form

Association of Analgesia Nociceptive Index with Pre-Operative Anxiety and Post-Cesarean Opioid Consumption: A Prospective Observational Study

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Neither the Principal Investigator nor the Co-Investigators have received financial compensation from any sponsor for the work required in doing this clinical research.

Emergency Telephone Number:

- During Office Hours (Mon-Fri; 8:30am-4:30pm): 604-875-2158, ask the Department of Anesthesia administrative assistant to page one of the study investigators.
- Outside Office Hours: 604-875-2161, ask the operator to page the Anesthesiologist on Call.

1. Invitation

You are being invited to take part in this research study because you are a healthy pregnant patient scheduled for a Cesarean delivery.

2. 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 or are presently receiving.

You should be aware that there is a difference for both you and your doctor between being a patient and being a research participant. As a patient, all medical procedures and treatments are carried out for your benefit only according to standard accepted practice. As a research participant, you and your doctor also must consider the requirements for the research study. This consent form describes the procedures that are being carried out for research purposes. Please review the consent document carefully when deciding whether or not you wish to be part of the research and sign this consent only if you accept being a research participant.

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

Please take time to read the following information carefully and to discuss it with your family, friends, and doctor before you decide.

3. Who is conducting this study?

This study is being conducted by the Department of Anesthesia at BC Women's Hospital in Vancouver, British Columbia. The Principal Investigator is Dr. Anton Chau and the study co-investigators are Mr. Cyrus Bhiladvala, Dr. Charles Prior, and Dr. Arianne Albert.

This study is not receiving funds from an external agency or sponsor and none of the study researchers have any conflicts of interest to disclose.

4. Background

The anesthetist's job revolves around managing and relieving their patient's pain, during and after surgery. High post-operative pain scores after caesarean sections have been linked to increased rates of post-partum depression, longer hospital stays, bad sleep, and a lowered ability to breastfeed. For these reasons, accurate prediction of post-operative pain is very important to obstetric anesthetists. Studies have shown that anxiety during and after operations correlates with high pain scores in recovery. If we can measure patient anxiety, we believe we can predict their pain.

Anxiety is hard to measure quickly and objectively. The Analgesia Nociception Index (ANI) monitor provides the anesthesia doctors with a look at the body's parasympathetic level through analysis of heart rate. The parasympathetic nervous system is the body's automatic "rest and digest" response, which is elevated when a patient is relaxed and happy. Depending on a patient's tolerance for stress, their parasympathetic "tone", or relaxation score, will drop. We have explored this idea in prospective clinical trials with the monitor, and found that ANI responds strongly to changes in emotional state.

We believe that changes in ANI score during their operation will be a strong indicator for post-operative pain. We are looking to recruit 40 participants from BC Women's Hospital.

5. What is the purpose of the study?

The goal of the study is to determine whether changes in ANI score greater than 30 points are a useful indicator of post-operative pain.

6. Who can participate in this study?

You may be able to participate in this study if*:*

- You are 19 years of age or older.
- You are healthy and greater or equal to 36 weeks pregnant.
- You are scheduled for an awake Cesarean delivery with spinal anesthesia

7. Who should not participate in this study?

You will not be eligible to participate in this study if:

- You have a medical condition that affects your heart and its rhythm.
- You have a family history of heart rhythm abnormalities.
- You are currently on any supplements or medications that influence your heart rhythm (a study member will discuss this with you).
- You are unable to give informed consent because of a language barrier.

8. What does the study involve?

Overall design of the study

The goal of the study is to determine whether repeated changes in ANI score greater than 30 points are a useful indicator of operative anxiety, and post-operative pain.

This study has an observational design, which means that your treatment plan will not be changed, but data will be collected from you as you pass through your procedure. If you choose to participate in this study, you will have one sticker placed near your right clavicle, and one on the lower left of your ribcage. These stickers will be attached in the pre-

operative room, and will remain on until you exit the post-anesthesia care unit (PACU). The study procedures will take no longer than standard clinical care and are complete when you exit the PACU.

9. What are my responsibilities?

In the pre-surgical care area, you will be requested to complete a questionnaire to assess your level of surgical anxiety.

Since this is an observational study, you are not responsible for changing your behavior for the duration of the study. If at any time you wish to withdraw, please inform the study member, and the stickers will be removed.

10. What are the possible harms and discomforts?

You may experience some discomfort related to the stickers and wires on your chest, but the study team will try their best to minimize this discomfort by strategically placing the stickers and removing them as soon as study procedures are complete.

11. What are the potential benefits of participating?

There are no direct benefits to you for being part of this study. However, we hope that the information learned from this study can be used in the future to benefit other women after their Cesarean delivery.

12. What are the alternatives to the study treatment?

If you choose not to participate in this study or to withdraw at any point, the medical care that you will receive will not be affected in any way. Your scheduled Cesarean delivery will proceed as normal with an anesthesiologist not involved in the study and you will receive all the care that is normally provided at BC Women's Hospital.

13. What if new information becomes available that may affect my decision to participate?

If you choose to enter this study and at a later date wish to withdraw, please contact **Cyrus Bhiladvala** at 604-875-2158. Your data will be deleted, and will not be analyzed in the study.

14. 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 decide to withdraw at a later time, you have the right to request the withdrawal of your information collected during the study. This request will be respected to the extent possible. Please note however that there may be exceptions where the data will not be able to be withdrawn for example where the data is no longer identifiable (meaning it cannot be linked in any way back to your identity). If you would like to request the withdrawal of your data, please let your study member know. If you decide to withdraw from the study and are interested, you also have the right to know what group you were assigned to.

15. Can I be asked to leave the study?

If you are not able to follow the requirements of the study or for any other reason, the study member may withdraw you from the study and will arrange for your care to continue as normal. On receiving new information about the treatment, your research member 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. If you are asked to leave the study, the reasons for this will be explained to you and you will have the opportunity to ask questions about this decision.

16. How 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 his or her designate by representatives of the University of British Columbia Children's and 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 participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity 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 ensure that your privacy is respected. You also have the legal 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.

17. What happens if something goes wrong?

By signing this form, you do not give up any of your legal rights and you do not release the study member, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan.

18. What will the study cost me?

All research-related medical care and treatment and any related tests that you will receive during your participation in this study will be provided at no cost to you.

You will not incur any personal expenses as a result of participation in this study, nor will you be paid for participating.

19. 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, or if you experience any adverse effects, you can contact Mr. Cyrus Bhiladvala (Research Assistant), or Dr. Anton Chau (Principal Investigator) at 604-875-2158. You can also reach the anesthesiologist on call at any time at 604-875-2161 (24-hour paging number).

20. Who do I contact if I have any questions or concerns about my rights as a participant?

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 (H19-03148) when contacting the Complaint Line so the staff can better assist you.

21. After the study is finished

We believe that this study will take about 6 months to complete. If you are interested in knowing the results of the study, please contact the Department of Anesthesia at 604-875-2158 and one of the study investigators will contact you.

22. Signatures

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Participant Consent

My signature on this consent form means:

- I have read and understood the information in this consent form.
- I have had enough time to think about the information provided.
- I have been able to ask for advice if needed.
- I have been able 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 purposes.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change 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 consent to participate in this study.

Participant's Signature	Printed name	Date

Investigator's Signature	Printed name	Study Role	Date