Appendix 3

Participant Information and Consent Form

1. Duration of urinary catheterization following cesarean deliveries under neuraxial anesthesia: a prospective cohort study (DUCC Study)

2. Study personnel

Principal Investigator: **Anton Chau, MD MMSC FRCPC**
Department of Anesthesia
BC Women's Hospital
Phone: 604-875-2158

Co-Investigators: **Aislynn Sharrock, BA (Hons.)**
Department of Anesthesia
BC Women's Hospital
Phone: 604-875-2158

Marianne Vidler, PhD
Obstetrics & Gynaecology
University of British Columbia
marianne.vidler@cw.bc.ca

Juliana Barrera, MD MSc FRCPC
Department of Anesthesia
BC Women's Hospital
Phone: 604-875-6076

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

Study Contact 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.

3. Invitation

You are being invited to take part in this research study because you underwent a cesarean delivery under neuraxial anesthesia at BC Women's Hospital.

4. 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.

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.

5. 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 Ms. Aislynn Sharrock, Dr. Marianne Vidler, and Dr. Juliana Barrera.

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

6. Background

In cesarean deliveries, urinary catheters are often used to help empty the bladder while patients have limited mobility. These catheters typically stay in during early recovery because certain pain medications can make it hard for patients to urinate. Recently, the Society of Obstetric Anesthesia and Perinatology (SOAP) recommended removing catheters within 6–12 hours after delivery to aid recovery. However, at BC Women's Hospital, a review found that catheters stayed in for an average of 19 to 19.4 hours, even when patients were mobile.

Leaving catheters in too long can increase the risk of urinary tract infections (UTIs), pain, and urination issues, which can delay recovery and extend hospital stays. An internal review showed that factors like patient anxiety may affect when catheters are removed. Postpartum anxiety affects around 9.9% to 20.7% of new mothers in the first year and is an important factor in recovery after a cesarean delivery.

7. What is the purpose of the study?

The main goal of this study is to look at how long urinary catheters stay in patients who had a cesarean delivery under spinal or epidural anesthesia, and what the score is from a questionnaire used to measure anxiety called the State Trait Anxiety Inventory (STAI-S), to see if there is a link between them.

8. 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 underwent a cesarean delivery (elective or emergency) at BC Women's Hospital.
- You received spinal or epidural anesthesia.
- You self-report a proficiency in speaking and reading English.

9. Who should not participate in this study?

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

- You refuse to participate.
- You are unable to give informed consent because of a language barrier.
- You underwent a different surgery (i.e. cervical cerclage) or delivery mode (i.e. operative vaginal delivery).
- You received a general anesthetic or had a conversion from spinal or epidural anesthesia to general anesthesia.

10. What does the study involve?

- **If You Decide to Join This Study: Specific Procedures**

If you agree to take part in this study, the procedures and visits you can expect will include the following:

- **Study Visit**

While you are recovering from your cesarean delivery in the postpartum ward at BC Women's Hospital, a member of our research team will approach you about the study at 24 (+/- 8) hours. You will be asked about your current experience of pain when moving and when at rest using a numeric rating scale between 0 (no pain) and 10 (worst pain imaginable). You will also be asked to answer if you have gotten up and moved since your procedure. After, you will be asked to fill out the STAI-S questionnaire regarding your current emotional state. You will answer questions about how anxious you feel right now on a scale from 1 (not at all) to 4 (very much so). The entire questionnaire should take you approximately 5-8 minutes, and the total time to participate is expected to take 15 minutes, which includes reading the study background and procedures, consent process and questionnaire. Your participation is voluntary. You may leave questions blank or stop at any time. The questionnaire will be provided in English.

If research staff observes findings through your data collection form that could be of potential clinical relevance (e.g., high pain or anxiety scores), you will be asked if you would like the research staff to relay this information to your circle of care. If you give us permission, we

will contact your most responsible physician (MRP) and/or nursing staff to relay the information on your data collection form to them.

- **Additional data collection for study (postpartum nurse and medical chart review)**

Because our study is looking at the duration of urinary catheterization and what factors may be influencing the time your urinary catheter is removed, we want to gather data from the postpartum nurse who took out your urinary catheter. In instances where a urinary catheter was left in beyond 16 hours, we will be approaching your assigned postpartum nurse to answer statements to help us understand what factors influenced their decision to remove your catheter. Additionally, we will be taking data from medical records from your cesarean delivery to further collect data on demographic information (specifically: age and cultural/ethnic heritage), obstetric information, anesthesia dosing information, and urinary catheter information. Only documentations pertinent to the data noted above will be abstracted.

11. What are the possible harms and discomforts?

As the postpartum period can be a time of vulnerability, the risks for this study are that the survey includes sensitive topics which may cause distress. You do not have to answer any questions that you are uncomfortable answering.

At the end of this consent form, you will find a list of resources related to postpartum mental health (specific to anxiety) and postpartum recovery and care if you wish to self-refer.

Additionally, if you have any concerns, we recommend you contact the Pacific Postpartum Support Society, the BC Mental Health Line or Health Link BC. The Pacific Postpartum Support Society provides phone and text support from trained counselors who specialize in mental health for new parents. The BC Mental Health Line is available 24/7, offering immediate and confidential help by phone and online. Health Link BC acts as a guide for health services and can connect callers to a nurse, dietitian, fitness expert, or pharmacist.

12. What are the potential benefits of participating?

There may not be direct benefit to you from taking part in this study. We hope that the information learned from this study can be used in the future to improve patient's recovery after a cesarean delivery under neuraxial anesthesia.

13. After the study is finished

We believe that this study will take about 9 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.

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) or where the data has been merged with other data. If you would like to request the withdrawal of your data, please let the principal investigator of the study know.

15. 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 designate and by representatives of UBC 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, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to the study team.

16. Future Use of Data

The prospective cohort study will be published in a medical journal and presented at conferences so that we can disseminate the findings within the medical community. It is our hope that this study will catalyze ongoing research to further enhance postpartum recovery following cesarean delivery under neuraxial anesthesia. There are no future uses planned for

the data beyond understanding factors associated with the duration of urinary catheterization following cesarean deliveries.

We only anticipate the Primary Investigator and study team members to have access to the data for the purposes of completing the objectives of this study.

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 principal investigator, 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 procedures 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. If I have questions about the study procedures during my participation, who should I speak to?

If you have any questions or desire further information about this study before or during participation you can contact Aislynn Sharrock (Co-Investigator) or 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 and/or have any concerns or complaints related to privacy, 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 (H24-03410) when contacting the Complaint Line so the staff can better assist you.

21. Future Contact

Would you like to be contacted once the study is completed so we can share the results with you through receiving a copy of the journal article and/or a summary of the results?

☐ Yes ☐ No Name: _____ Email Address: _____

Are you interested in learning about other studies conducted by Dr. Anton Chau in the future?

☐ Yes ☐ No Initials_____

Note that for any future studies, a separate consent form will be provided to you for review.

22. Signatures

Duration of urinary catheterization following cesarean deliveries under neuraxial anesthesia: a prospective cohort study (DUCC Study)

Participant Consent

My signature on this consent form means:

- I have read and understood the information in this consent form.
- I have been able to ask questions and have had satisfactory responses to my questions.
- 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.
- 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 authorize access to my health records as described in this consent form.

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

I consent to participate in this study.

_____	_____	_____
Participant's Signature	Printed name	Date

_____	_____	_____	_____
Signature of Person Obtaining Consent	Printed name	Study Role	Date