a place of mind
THE UNIVERSITY OF BRITISH COLUMBIA

PARTICIPANT INFORMATION AND CONSENT FORM (ADULT)
DOMPERIDONE USE AND CARDIAC SAFETY DURING BREASTFEEDING

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Sponsor: Canadian Institutes of Health Research

Invitation

We invite you to take part in a research study called *Domperidone Use and Cardiac Safety During Breastfeeding*. Doctors and scientists at the University of British Columbia are conducting a research study to learn how domperidone is prescribed to and used in breastfeeding parents and what characteristics might make a breastfeeding parent more or less likely to develop QT prolongation. You are being invited to take part in this research because you will, or have already receive domperidone to stimulate milk production.

Your participation is voluntary

Your participation is voluntary. It is up to you to decide whether or not to take part in this study. 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, and what will happen during the study. The possible benefits, risks, and discomforts are described.

If you wish to participate, you will be asked to sign this form. If you do decide to take part in this study, you are free to withdraw at any later time and without giving any reasons for your decision. If you do not wish to participate, you do not have to provide any reasons for your decision not to participate nor will you lose the benefit of any medical care to which you are entitled or are presently receiving. Please take time to read the following information carefully and to discuss it with your family, friends, and doctor before you decide.

Who is conducting the study?

Researchers at the University of British Columbia are leading this study. Funding for this study comes from the Canadian Institutes of Health Research. There are no conflicts of interest between the researchers and the funders of this project.

Background

Domperidone is a drug that can be used to increase milk production in breastfeeding parents. While domperidone is generally considered to be safe, a small number of breastfeeding parents may be at a higher risk for developing QT prolongation. QT prolongation occurs when the heart muscle takes longer to contract and relax than usual, which can lead to sudden cardiac arrest. Various health factors and medications can also increase the risk of a person developing QT

prolongation while taking domperidone. We are interested in conducting an observational study to learn how domperidone is prescribed to and used in breastfeeding parents, and what characteristics might make a breastfeeding parent more or less likely to develop QT prolongation.

What is the purpose of the study?

Data collected from this study will be used to explore how domperidone is prescribed to and used in breastfeeding people and understand the risk of QT prolongation, other adverse effects, and related topics. Information that does not directly identify you may be published and shared with other researchers from around the world for research studies that will be planned in the future. This information will always be shared securely and confidentially.

Who can participate in the study?

- Breastfeeding parents who will be new domperidone users and breastfeeding parents who are already using domperidone to stimulate milk production at the time of enrolment can participate in the study

What does this study involve?

If you agree to take part in this study, you can expect that:

- After your treating physician has determined that you can participate in the study, a study staff member will explain the study to you. After all your questions have been answered, they will give you a copy of the consent form to review and sign.
- You will be asked some questions about your medical history, the prescription drug(s) you are currently taking, the prescription drug(s) you have taken, and any side affects you have experienced while taking domperidone.
- A study staff member will apply electrocardiogram (ECG) electrodes (sticky patches) to your body so that they can measure your heart rate. The ECGs will be done after your regularly scheduled breastfeeding medicine appointment. An ECG will be done at the time of enrolment, after any dose changes (only if you are already in the clinic for a regularly scheduled appointment), and at the completion of domperidone treatment. Your treating physician will inform the study team if your dose is adjusted and/or when domperidone is discontinued. It will take 5 minutes to conduct each ECG.
    - NOTE: The administration of domperidone and any dose changes that occur will be part of your clinical care. You do not need to wait to take your domperidone or take it at specific times to participate in the study.
- Any prolongation of QT beyond 480ms or any cardiac abnormality observed will be discussed with your treating physician. Your treating physician will decide what, if anything, should be done or modified in terms of domperidone use.

What are the possible harms and discomforts?

Electrocardiograms (ECGs) are safe, noninvasive, painless tests and have no major risks. The electrodes (sticky patches) that connect the sensors to your chest do not send out electric shocks. You may develop a mild skin irritation where the sticky patches are attached.

What are the potential benefits of participating?
There may not be direct benefit to you from taking part in this study. The study doctors hope that the information learned from this study can be used in the future to benefit other breastfeeding parents who take domperidone.

What happens after the study is finished?
Study results will be communicated to participants in a meaningful and accessible way. You will be asked if you want to receive information about study results. You can check the "yes" box and provide your email address, or check the "no" box. After the study is completed, a lay summary will be created. If you answered yes to the above question, you will be sent the lay summary and a link to the journal article via email. You will also be able to obtain general information on the progress of this research project by visiting our official website: www.cpnds.ubc.ca.

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 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 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.

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's Clinical Research Ethics Board and the Canadian Institutes of Health Research 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 (for example, it will not include your Personal Health Number, SIN, or your initials). 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. Research related information will be kept for 25 years after the last participant is enrolled. All study records will then be destroyed.

You may use email to communicate about this research study. The research team will use best efforts to keep your information confidential. However, there are always some risks of disclosure when using email and you should be aware that some email services may store the contents of your email account outside of Canada, where privacy and data security standards

may be different than they are in Canada. If you have questions or would like to stop receiving research communication via email, please contact Dr. Bruce Carleton, Principal Investigator, by phone at 604-878-4131 (toll free: 1-877-878-4131) or bcarleton@popi.ubc.ca.

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 the study team.

Final results of this study will be published in scientific journals. All results will be published in summary form. No individual participants can be identified. No individual participant results will be shown.

Disclosure of Race/Ethnicity
Studies involving humans now routinely collect information on race and ethnic origin as well as other characteristics of individuals because these characteristics may influence how people respond to different medications. You should be aware that providing this information is not mandatory.

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 and/or by the Canadian Institutes of Health Research.

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. There is no reimbursement or remuneration for participating in this study.

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, or if you experience any adverse effects, you can contact Dr. Bruce Carleton by phone at 604-878-4131 (toll free: 1-877-878-4131).

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, experiences while participating in this study, or your 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 (H23-03166) when contacting the Complaint Line so the staff can better assist you.”

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

I consent to participate in this study.

_____	_____	_____
Participant Signature	Printed Name	Date

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

Optional:

1. **I consent to the study investigators collecting information on my country(ies) of family origin.**

Yes ☐ No ☐

2. I would like to receive information about study results.

Yes ☐ No ☐

Email address: _____

Phone Number: _____

3. There is a chance that during or after this study the study team will find other questions needing answers that require future studies. If I am willing to hear about these future studies, I will mark the "yes" box. This does not mean that I will have to take part in a new study, just that the study team will let me know about it. If I do not want to be contacted about new studies, I will mark the "no" box." Are you willing to be contacted by the researchers for future studies?

Yes ☐ No ☐