Information Letter & Consent Form

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Project: A mixed method community action study exploring "life-cycle" healthcare transitions with Canadians experiencing intersex variations

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Why are we doing this project?

The ultimate goal of this study is to understand what are the current experiences of health care transitions for both 'providers of health care' and 'individuals with intersex variation'. With this knowledge we hope to better understand how to develop timely, effective, and evidence-informed transition healthcare for Canadians with intersex, throughout their lives.

There is much debate around the terms used to define people who have developmental or congenital health conditions that affect their hormones and the development of their reproductive organs. The Canadian Institute of Health Research (CIHR) used the term interesex yet in line with others we acknowledge differences or diversity of sex development (DSD). We also acknowledge that individuals have the right to self-define as Intersex. Being Intersex means an individual can have variations in sex characteristics (i.e., genitals, hormones, chromosomes, reproductive organs) that do not seem to fit typical binary notions of male or female bodies which vary from the established norms for 'male' and 'female'. Between 0.05%-4% of the population has some intersex variation, with some variations being as common as twins or red hair. Most intersex variations are natural and healthy, but they (and their medical treatments typically from a very early age) can influence physical appearance, function, fertility and at times sexual wellbeing as well as interactions with health care providers over an individuals lifetime.

For Canadians with intersex variations health care access at times of transition (i.e., child-adolescent, leaving paediatric services, specialist-care-to-primary-care,

specialist-to-specialist care, adult provider-to-adult-provider) coupled with impaired health literacy as a result of a 'lack of' or 'access to' educational resources or information can compromise future self-management capacity, wellness and the path towards lifelong well-being. A lack of attention to intersex-life-cycle transitions and the impact sex and gender choices have on navigating access to health services (i.e. fertility, menstrual management, menopause, cardio-vascular health promotion information, functionality in demanding jobs for those with cortisol biosynthesis challenges, medication need adjustment etc.) can contribute to frustration, poor specific (variation focused) and altered general daily-living (physical, social and mental) health outcomes.

This study aims to analyze existing current knowledge and evidence of transition care provided 'by healthcare' and 'received by' individuals with intersex in order to design a pilot survey looking at transition care for Canadians with intersex.

This study is being led by Dr. Caroline Sanders at the University of Northern British Columbia with co-investigators at BC Women's Hospital, Ghent University, and Macquarie University and collaborators at BC Children's Hospital and Wilfred Laurier University.

Why are you being asked to take part in this study?
You are being asked to take part in this study because of your experience seeking healthcare services during life-cycle transitions or as someone who is involved in provision of health services (e.g. caregivers, doctors such as endocrinologists, primary care providers, nurses, psychologists, social workers, policy makers or others).

Participation in this study is voluntary, you can choose not to offer any insights or answer any questions that arise during wither the stakeholder or reference group interactions that make you feel uncomfortable. You are free to withdraw from this study at any time, without giving a reason. If you withdraw from the study, any information you have provided up to this point can also be withdrawn and securely destroyed, **unless you explicitly consent to your information being retained and analyzed.**

What will happen during the study?
If you agree to participate, here is how the study will be conducted:

- The study team will ask you to take part in a consultation session (stakeholder event - for health care providers **OR** individuals with intersex variation) in either Ontario [insert date, time, venue] or in British Columbia [insert date, time, venue]. Ideally, this is in person or we can use video conferencing.
- **NOTE** Providers and individuals with an intersex variation will be invited to separate consultation sessions.
- **AT** any stage of working with the study team you will be given time to ask any questions you have. In preparation for our consultation sessions we will send you: directions, travel claim forms, and agenda for our time together, any materials to review.
- Consultations will be facilitated by a minimum of two members of the study team
- We will ask to record the consultation as to ensure we capture the conversation as clearly as possible. This audio will be transcribed by someone who has signed a confidentiality agreement. Once the transcription is complete and has been checked by

the study team the audio files will be destroyed. If all members of the group do not agree to an audio recording we will keep handwritten notes which will be destroyed once reviewed and agreed by the study team.

- We anticipate that the consultation meeting will last for between 3-6 hours, refreshments will be provided, but it could be shorter than this.
- Following completion of this consultation meeting (stakeholder event) you will be asked if you wish to be involved in a series of up to four reference group meetings. The goal of the reference group meetings are to use the information from the stakeholder consultation to draft a pilot transition experiences-pilot survey which, we will later use across Canada.
- It is hoped that the reference group will include both healthcare providers **AND** individuals with an intersex variation.
- The reference group meetings will take place either face-to-face, depending on where you live, over the telephone, using video conferencing or email to offer feedback and ask questions about the pilot transition survey.

What are the risks and benefits of participating in the study?
We do not think there is anything in this study that could harm you. Some of the questions we ask may seem sensitive or personal. You do not have to answer any question if you do not want to. If, at any point in the study, you feel uncomfortable or upset and wish to end your participation, please notify the researcher immediately and your wishes will be respected.

Potential risks identified include emotional/psychological risk associated with talking about potentially sensitive subject matter (e.g. may feel uncomfortable, upset, or embarrassed). A social risk that could arise is a loss of privacy; any participant that attends the stakeholder event / reference focus group meeting cannot be guaranteed anonymity based on the fact that other participants are present. Potential benefits identified include networking with individuals with related experiences.

While we do not think taking part in this study will help you it is possible that you may meet and talk to others who share similar experiences as a healthcare provider or recipients of health care. This may increase your networking with others. You may choose to use this approach to stay connected with those you meet at a consultation session. In the future, others may benefit from what we learn in this study.

As a part of this study you may wish to become involved in future patient oriented research (http://www.cihr-irsc.gc.ca/e/41204.html and https://www.popdata.bc.ca/projects/BCSUPPORTUnit). We believe that patients need to be involved in all aspects of research (starting at the beginning, being part of the journey and sharing what we find at the end). You have the opportunity at the end of the interview or at the workshop to learn more about this new approach to working together in Canada.

How will your data be used and your privacy maintained?
Your privacy will be respected. Information that discloses your identity will not be released without your consent. Participant confidentiality will be maintained, yet at any point in the stakeholder event or at reference group meetings any participant may choose to share

about their participation in the event, we cannot account for this and therefore anonymity cannot be guaranteed.

Any recorded information will be kept securely on the University of Northern British Columbia internal network and only accessible to the principal investigator, co-investigators and designated research associates/assistants. Research documents will be shared between the principal investigator, co-investigators and designated research associates/assistants using the secure end-to-end encrypted data sharing platform Sync which is compliant with Canadian data residency requirements.

- All documents will be identified only by code number and kept in a locked filing cabinet in a locked office and/ or on a password-protected computer at the University of Northern British Columbia. Team members will be able to access anonymized data through a secure password encrypted server housed at UNBC.
- Participants will not be identified by name in any reports of the completed study.
- We may use direct quotes from our consultation. You will not be identified by name and will have been given a pseudonym.
- The information gathered from this study will be kept for five years. It will then be securely destroyed [e.g. by shredding paper files, deleting digital files].

Compensation

We will pay you for your participation in the interview part of this study. A voucher following the study interview will be posted to you. It is anticipated that this could be for a phone network of your choice (depending on the network used) or alternative up to a value of $80.00.

We will pay reasonable travel costs [bus or taxi fare or reasonable airfare, parking, telephone provider cost, lunch] to participate in the workshop if this is delivered in a face-to-face format.

Study Results

We want our work to be visible throughout our study. We anticipate using our newly developed webpage http://cahcanada.ca/ supported via REACH funding from the Michael Smith Health Foundation to post bi-monthly updates. The final report will be published publicly online through as well as shared with you via email, should you wish to receive this.

We aim to publish in academic journal(s), reports to our funding partner (CIHR), presentation at national and international conferences and share with support group networks across Canada and our global partners.

Questions, Concerns or Complaints about the project

If you have any questions about what we are asking of you, please contact the Principal Investigator, Dr. Caroline Sanders at 250-960-5848 or by email at caroline.sanders@unbc.ca.

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 UNBC Office of Research at 250‑960‑6735 or by e-mail at reb@unbc.ca. Research Participant Complaint Line in the UBC

Office of Research Ethics at 604-822-8598 or if long distance e-mail RSIL@ors.ubc.ca or call toll free 1-877-822-8598. Please reference the study number H19-01764 when contacting the Complaint Line so the staff can better assist you.

Participant Consent and Withdrawal

Taking part in this study is entirely up to you. You have the right to refuse to participate in this study, and if you decide to take part, you may choose to withdraw from the study at any time without giving a reason and without any negative impact on your personal status (e.g. employment, class standing, access to further services from health providers, etc.). If you withdraw from the study, any information you have provided up to this point can also be withdrawn and securely destroyed, unless you explicitly consent to your information being retained and analysed. At the time of withdrawal we will ask for your consent to retain your data or destroy your data. If the data has already been analysed withdrawal of information may not be possible as it will have been integrated in outputs.

Your signature or verbal confirmation recorded below indicates that you consent to participate in this study, and that you have received a copy of this consent form for your own records.

CONSENT (please indicate your answer)

I have read or been described the information presented in the information letter about the project:

YES NO

I have had the opportunity to ask questions about my involvement in this project and to receive additional details I requested.

YES NO

I understand that if I agree to participate in this project, I may withdraw from the project at any time up until the report completion, with no consequences of any kind. I have been given a copy of this form.

YES NO

I agree to be recorded.

YES NO

Follow-up information can be sent to me at the following email or mailing address:

YES NO

Signature (**or note of verbal consent**): _____

Name of Participant (Printed): _____

Date: _____

Email Address: _____

Resources and Support

In the event that you experience distress or require help as a result of this research, please contact your healthcare provider or use the information provided below.

Free Resources	
Crisis Centre – Distress Line	Tel: 1-866-661-3311
Crisis Prevention, Intervention and Information Centre	Tel: 1-888-562-1214
Fraser Health Crisis Line	Tel: 1-877-820-7444
Youth in BC Crisis Line	Tel: 1-866-872-0113
Other Resources	
BC Association of Clinical Counsellors	Tel: 1-800-909-6305 or www.bc-counsellors.org
Inner Light Counselling, Victoria, BC	Tel: 1-891-7452
Insight Counselling, Kelowna, BC	Tel: 1-753-5874
Jericho Counselling, Vancouver, BC	Tel: 1-604-537-4246
Journey Counselling Services, Victoria, BC	Tel: 1-250-885-0506
MindWise Counselling, Kamloops, BC	Tel: 1-250-819-1376

Northern Counselling and EMDR, Prince George, BC	Tel: 1-250-997-1755
Walmsley and Associates, Prince George, BC	Tel: 1-250-564-1000
Willow Tree Counselling, Vancouver, BC	Tel: 1-250-521-3404