ADOLESCENT INFORMATION and ASSENT FORM
(generally for participants aged 14-18 years)

DIAGNOSIS OF GENETIC CONDITIONS IN INDIGENOUS FAMILIES

1. Who is doing the study?
The doctors in charge of this study are **Dr. Laura Arbour** (Principal Investigator and Victoria site lead) and **Dr. Anna Lehman** (Co-Principal Investigator and Vancouver site lead). The principal investigator and site lead in Calgary is **Dr. Francois Bernier**. There are many other doctors and other health professionals involved in this study. The person who is the main contact for me is:

Calgary site – Brenda McInnes (genetic counsellor) and **Dr. Francois Bernier** at: 403-955-7028, Brenda.McInnes@ahs.ca

2. Invitation
I am being invited to take part in this research study because I have a health condition, or someone in my family has a health condition, that is thought to be genetic. Although genetic conditions occur in all groups of people, only Indigenous families are being invited into this study.

This form explains the study so that I can decide if I want to take part or not. It is up to me if I want to be in this study. No one will make me be part of the study, and no one will get mad at me if I don't want to be in it.

3. Do I have to be in this study?
I do not have to participate in this study if I don't want to. If I choose to participate, I can stop being in the study at any time. My healthcare team will take care of me as they have in the past, regardless of whether I am in the study or not.

If I want to participate in this study, I will be asked to sign this form. My parent/guardian will need to sign a consent form before I join the study; but I do not have to participate even if they sign the consent form. The researchers will not enrol me into the study unless I agree to do so.

I should take time to read the following information carefully and to talk it over with my family, and if I wish, my doctor, before I decide. I understand that I should feel free to talk to the study team if anything is not clear. Even if I agree now to be part of the study, I can change my mind later. I can ask the study team any questions I may have at any time during my study participation.

4. Why is this study being done?
The goal of the study is to try to find the cause of health conditions that we don't yet know much about. This study will do a type of testing called **'whole genome sequencing' (WGS)**

to check if the health condition in my family is caused by changes in **genes**. Genes are the instructions in every cell of our body that tell our bodies how to work. We inherited half of our genes from our mother, and the other half from our father. Genes are made up of letters and words, similar to a book. If there is a spelling mistake in a gene (called a '**gene change'**), it can sometimes cause a health problem. WGS will search for gene change(s) that might explain the condition in my family.

We are inviting only Indigenous families into this study to try to reduce the barriers that many Indigenous families face when trying to get WGS testing done.

5. Why are you inviting me to be in this study?
I am being invited to be in the study because I have, or someone in my family has, a health condition that the doctors don't fully understand. The study doctors think that the health condition in my family may be genetic, and that WGS may be able to find the gene changes causing the condition.

6. What will happen to me in this study?
If I agree to be in this study, some or all of the steps below will be done. Each family is a little different, so not everybody will have the exact same steps done. The study doctors will let me know which steps to expect before I sign this form.

Meeting with the study genetic counsellor
The first step is meeting with the study genetic counsellor, who will explain the study to me, talk about the possible pros and cons of joining the study, and answer any questions I may have.

Looking at my medical records
The study team will review my medical records, to fully understand my health and find out what testing I have already had in the past.

A blood test
I will be asked to give a small blood sample so that my genes can be tested. About 1 teaspoon of blood will be taken from a vein in my arm using a needle. The doctors know that this can be scary for some people and it can feel like a prick. I can ask for a spray or cream on my skin before the test to numb the skin so it doesn't hurt.
In some cases, a saliva (spit) sample or cheek swab (wiping the inside of the mouth) may be done instead of a blood sample. If there are samples (tissue or DNA) that have been previously banked, researchers may be able to use those instead.

Photographs
The study doctors may wish to take photos of me. Sometimes it is helpful to take photos to show the features of a health condition, rather than to describe them in writing. If photos are taken of me, they will not be used for anything other than this study and will not be shared with others without my permission.

Additional tests

Sometimes the study doctors wish to collect other samples from participants to help understand the condition. Examples include hair sample, skin sample, urine (pee), or a cheek swab (wiping the inside of the mouth). If the doctors wish to collect any of these extra samples from me, they will explain the reason for this and I will have the choice to say 'yes' or 'no'.

Results

When the results of my WGS test are back, the study team will give my test results to my doctor who referred me to the study. My doctor will then share the results with my family, and the study genetic counsellor will also be available to help us understand the results.

7. Can anything bad happen to me?

If I have a blood test, it may hurt a little, but it won't last long. Sometimes having a blood test causes a bruise on the arm, which will go away.

If I learn that I have a gene variant causing my health condition, there may be other family members, including those alive now or those who may be born in the future, who share the same variant and are at risk of having the same condition. This information may be helpful to me and my relatives, but there is also a chance it may cause worry or stress. For some people, genetic test results influence their decision to have a child in the future or affect other lifestyle decisions.

If I carry a gene change causing a health condition and choose to share my test result with others, there is a chance it could lead to discrimination towards me and/or my relatives. There is a new law in Canada that makes it illegal for employers and insurance companies to ask for my genetic test results or to use my genetic test results against me (for example, they cannot use this information to decide whether to offer me life insurance or whether to hire me for a job). Although this law is helpful, it does not stop insurance companies from using information about my current symptoms or family history of a health condition, or the results of *other types of medical tests* to decide if they will insure me (even if that health condition has a genetic basis). Also, laws sometimes change over time, so no one can guarantee that this law will always be in place to protect me.

A genetic counsellor on the study team is available to discuss the possible benefits and harms of WGS testing with me and my family and help us understand what my results might mean for me and my family.

8. What will the results of the study mean to me?

No one knows whether the results of this study will help me or my family. It is possible that I will get a better understanding of the health condition that affects me or my family members. Some people find it helpful when they learn the reason for their health condition. If a genetic cause for the condition is found, it may help doctors decide the best health care for me or my family members. It is unlikely that this study will cure the condition in my family.

9. Who will know I am in this study?

My privacy will be respected. Unless I allow them to, the study team will not tell anybody else (besides my doctor who referred me to the study) that I am or have been a part of this study. They will not release any of my research information that could be used to identify me to anybody else, unless they are required to do so by law. For example, researchers are required to report if a participant is thought to be at risk for harming him/herself or others.

In order to protect my privacy, the study team will remove any information that could identify me (such as my name, date of birth, community etc) from my research data, samples, and photographs. Instead of my name appearing on them, the study team will use a **study code** to label my study information and samples. That way, my identity will be kept private. Only Dr. Laura Arbour, Dr. Anna Lehman, and the study team members working closely with them will be able to link my study code to my name. The list linking my study code to my identity will be kept in a password-protected file on a computer server with strict security measures.

When the study is finished, the study doctors will write a report about what was learned. This report will not say my name or that I was in the study.

If WGS finds a gene change in me that explains the reason for my condition or can help my doctors provide medical care for me, then my genetic test result will need to be confirmed in a clinical (non-research) lab before the result is given back to my referring doctor and my family. If the clinical lab confirms my gene change, the lab will write a clinical report of my result that has my name and other identifying information on it. At that point, my genetic test result will not stay only in the research study, but will also become a result that is part of my health records and my doctors/ healthcare team (now and in the future) will be able to see it if they need that information for my health care. Importantly there are laws in place to protect the privacy of my health records and to stop my results from being shared outside of the medical system.

10. What will the study cost me?
All research-related medical care and tests that I will receive during my participation in this study will be provided at no cost to me.

11. Who do I contact if I have questions about the study during my participation?
If I ever have any questions about the study, I can contact the following study team member:

Calgary Site: Brenda McInnes e-mail: Brenda.McInnes@ahs.ca, phone: 403-955-7028

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

If I have any questions concerning my rights as a possible participant in this research, or research in general, I can contact the Chair of the Conjoint Health Research Ethics Board, University of Calgary at (403) 220-7990.

If I have any concerns or complaints about my rights as a research participant and/or my experiences while participating in this study, I can also 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). By giving the study reference number (H18-00726) when I call the Complaint Line, the staff will be better able to help me.

I can also contact the Vancouver Island Health Authority (VIHA) Research Ethics Board at 250-519-6726; researchethics@viha.ca

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PARTICIPANT ASSENT

My signature on this assent form means:

- I have read and understood the information on this assent form.
- I have had enough time to think about the information provided.
- I have had the chance to ask questions and have had acceptable answers to my questions
- I understand that all the information collected from me will be kept confidential and that the results will only be used for the purposes of this study.
- I understand that participation in this study is voluntary. I am completely free to refuse to participate or to stop participating in this study at any time, and this will not change the quality of care that I receive.
- I authorize access to my health records as described in this assent form.
- I understand that there is no guarantee that this study will provide any benefits to me.
- I understand that I can continue to ask questions, at any time, about my participation in the study.
- I understand that if a gene change is found in me that explains the reason for my health condition or affects my medical care, then my genetic test result will become part of my health records which all my doctors/healthcare team can look at.
- I understand that if I put my name at the end of this form, it means that I agree to be in this study.

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

I agree to participate in this study.

_____	_____	_____
Participant's printed name	Participant's signature	Date

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OPTIONAL ASSENT CHECKBOXES:

OPTION 1 –Photographs: Photographs of me, including photos of my face, may help the study doctors better understand the condition in my family and help with the interpretation of my genetic results. Any photos taken will only be viewed by the study team members, and will have the same privacy protections as the rest of my research information. I can choose whether I agree to have photos taken for the purposes of this study by marking either 'yes' or 'no' below.

I agree to have photos taken for the purposes of this research study:

□ **YES**
□ **NO**

OPTION 2 – Re-contact for Future studies : 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."

I am willing to be contacted by the researchers for future studies:

□ **YES, I agree** to be re-contacted about future studies.

□ **NO, I do NOT agree** to be re-contacted about future studies.