PCGL-IBVL Consent Template to Support Indigenous Data Sovereignty for CPHI Projects

Additional consent options for Indigenous participants

The Pan-Canadian Genome Library (PCGL) stores data from genomic research studies whose participants have provided consent to have their data stored in a secure environment. Acting like a public library, the PCGL stores and shares data, with the goal to preserve Canada's genomic data and to help researchers use it to make new discoveries, through open and controlled access options. This includes developing a Canadian 'genomic variation database' (documenting genetic changes that occur naturally in our country's population) which is especially important as reference data to understand genetic testing results which aim to provide a precise diagnosis for patients with genetic conditions.

The PCGL respects the rights of Indigenous peoples in Canada (First Nations, Inuit and Métis) to free, prior, and informed consent, as well as self-determination, including the ability to control their own data). Therefore, the PCGL partnered with the Silent Genomes Project (SGP) Indigenous Background Variant Library (IBVL), which is an Indigenous led distinct component of the PCGL providing Indigenous individuals and communities with an opportunity for Indigenous protection and oversight of clinical and research use of data. The IBVL is an Indigenous governed genomic database with strict access controls that supports accurate diagnosis and equitable access to genomic medicine and research for Indigenous individuals and communities. The IBVL is connected to the PCGL but is a distinct entity (data is not shared between the two databases) providing the opportunity for Indigenous-specific governance.

This consent form includes **additional consent options on the signature page for individuals who identify as Indigenous. This is about the use of data beyond this Name CPHI project and whether you wish to have it used to develop background reference information aimed to improve diagnosis, and to be used as part of future research. If so, you also have the opportunity for Indigenous governance over your data.**

The options will include: 1) data will be shared with both the IBVL and the PCGL, 2) shared only with IBVL but not the PCGL, 3) shared with PCGL but not the IBVL, or 4) not shared with the IBVL or the PCGL. Any data shared with the PCGL will have Indigenous identifiers removed - given the potential for sharing data which is held within the PCGL. Your choice will be respected, and your participation in **Name CPHI project** will not be affected by your decision.

If you are Indigenous and indicate in the additional consent option that you want Indigenous governance, please note: The IBVL Governance Committee chairs and members are largely First Nations and Metis, all ensuring Indigenous values of data sovereignty are upheld in the collection and storage of data, its use as reference data for clinical diagnostic purposes, and for future research relevant to Indigenous health. All research proposed for use of data in the IBVL is reviewed by the IBVL Governance Committee. To develop the governance process, the SGP team worked closely with the International Indigenous Genomics Advisory Committee and the Silent Genomes Indigenous Rare Disease Diagnosis Steering Committee (S-GIRDD Steering Committee). The S-GIRDD was developed in 2020 guiding the secure development of the IBVL. In 2025 the S-GIRDD then transitioned into the IBVL Governance Committee as the IBVL was launched. For more information about the Silent Genomes Project, the IBVL and its governance please visit:

- https://www.bcchr.ca/silent-genomes-project/our-team/iigac
- https://www.bcchr.ca/silent-genomes-project/ibvl/general-information-ibvl-overview
- https://www.bcchr.ca/silent-genomes-project/our-team/sg-ibvl-governance-committee

Do you identify as Indigenous?

☐ Yes

☐ No

☐ Prefer not to answer

If you have indicated YES to identifying as Indigenous, you are invited to answer the following question, please check all that apply:

☐ Yes, First Nations

☐ Yes, Inuk/Inuit^
If you have answered yes to Inuk/Inuit, you have the option of providing the

land claims region you are registered[1]: ____________________

☐ Yes, Métis

☐ Yes, "other Indigenous" (optional to provide name of your Indigenous group):

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☐ Prefer not to answer

☐ Do not know

If you have indicated **YES to identifying as Indigenous**, please indicate your preference below regarding the choice of participation in the IBVL and/or the PCGL. Your choice will be respected, and your participation in the **Name CPHI project** will not be affected by your decision.

Please choose one option only:

☐ I want my genomic and health data transferred to the IBVL which will be under Indigenous governance, and in addition, my genomic and health data (without any Indigenous identifier/s) transferred to the PCGL.

☐ I want my genomic and health data transferred to the IBVL which will be under Indigenous governance but not to the PCGL.

☐ I want my genomic and health data (without any Indigenous identifier/s) transferred to the PCGL but not the IBVL.

☐ I do not want my genomic and health data shared with the IBVL or the PCGL.

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[1] This option is provided after discussion with Inuit leadership in order to enable research specific to land claim regions which could be beneficial, and this also provides the opportunity to re-patriate data in the future on a regional basis.

Appendix

Table 1 sets out the organizations that may access your specific project-related data and for what purposes. By signing this form, and depending on the option you selected, you are authorizing such access.

Table 1: Access to your project-related data

WHO	WHAT	WHERE	PURPOSE
Name CPHI project	Project-related records and data (including your medical records) that include information that can identify you	Canada	[Add a project-specific purpose statement] [Add project specific plans for Indigenous governance for those requesting] Project personnel will be in charge of collecting the data and removing any information that is directly identifiable before sharing this to the PCGL and/or IBVL if you consented to this being done.
Pan-Canadian Genome Library (PCGL)	Genomic data and limited health data	Canada	Sharing genomic data to build a national, secure, and diverse resource that is Canadian-specific - that researchers and clinicians can use to better understand how genetics affects health and disease. Controlled-data access policies are in place and approved research may be transferred to other researchers, internationally and commercially. Indigenous data governance is not specifically available however researchers are required to adhere to common standards of research practice with Indigenous people in Canada such as the TCPS2 chapter 9[2], and international

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[2] Researchers are required to adhere to common standards of research practice in Canada such as the TCPS2 Chapter 9 which requires Indigenous community involvement when research impacts on a community, encourages Indigenous researcher leadership and capacity building, and requires Indigenous engagement and governance for all Indigenous specific analysis. https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter9-chapitre9.html.

			Indigenous data sovereignty (IDS) standards such as the CARE Principles.[3]
Indigenous Background Variant Library (IBVL)	Genomic data and limited health data	Canada	The IBVL is an Indigenous governed genomic database with strict access controls that supports accurate diagnosis and equitable access to genomic medicine and research for Indigenous Peoples and communities. All research requests are assessed for relevance to Indigenous Health and risk by the Indigenous governance committee. Data will not be transferred to other researchers, but approved data use will be supported by the Silent Genomes team to support Indigenous data protection.[4]

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[3] See Global Indigenous Data Alliance CARE Principles (Collective benefit, Authority to control, Responsibility and Ethics) https://www.gida-global.org/care

[4] Researchers are required to adhere to common standards of research practice in Canada such as the TCPS2 Chapter 9 which requires Indigenous community involvement when research impacts on a community, encourages Indigenous researcher leadership and capacity building, and requires Indigenous engagement and governance for all Indigenous specific analysis. https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter9-chapitre9.html.