PCGL Partnerships Framework

1. Purpose

The purpose of the Partnerships Framework (hereafter ‘the Framework’) is to present both the core principles and key partnership requirements of the Pan-Canadian Genome Library (thereafter ‘PCGL’). The Framework is also intended to foster transparency and trust in the PCGL.

This Framework outlines mutually beneficial, equitable, and principled partnership requirements for the PCGL, and more broadly, helps ensure a working culture that supports the mutual success of these partnerships. It should be interpreted in light of applicable Canadian laws and ethics guidelines, as well as the additional guidelines and standards adopted by the PCGL. The general requirements provided in the Framework are intended to be completed by more specific clauses within bilateral partnership agreements.

Framework version 1.2 applies until October 28, 2026. A revised Framework will be published at that time to update sections 6 and 7 in light of most recent scientific developments. After this date, the Framework will be updated on a yearly basis.

2. Background

With its world-leading genomics expertise, Canada has established foundational projects and datasets representing research and clinically derived genome sequences including HostSeq, Marathon of Hope Cancer Centres Network, All for One, and Silent Genomes. The PCGL is the next step in genomics advancement — a pan-Canadian database of genomic data supported by the Canadian Institutes of Health Research (CIHR), Genome Canada (GC) and partners. The central goal of the PCGL is to provide resources for researchers to understand the contribution of genomics to a wide range of diseases from childhood inherited diseases to heart diseases and stroke, diabetes, infectious diseases, neurological diseases, mental illnesses, and cancer. This will enable the establishment of a ‘real-time’ precision learning health care system, supporting more personalized diagnoses, improved treatments of individual patients and contributing to the discovery of new treatments and potential cures for medical conditions.

The promising potential of partnerships for the PCGL does not mean that these collaborations should proceed arbitrarily. The choice of our partners could lead to skepticism about the integrity of the PCGL, and this reality should be given due consideration. Media publication of data misuse and conflicts of interest can feed into public skepticism of research and undermine trust in science. By adopting a responsible attitude towards partnerships and adhering to robust ethical standards, PCGL will build lasting, productive, partnerships and foster public trust.

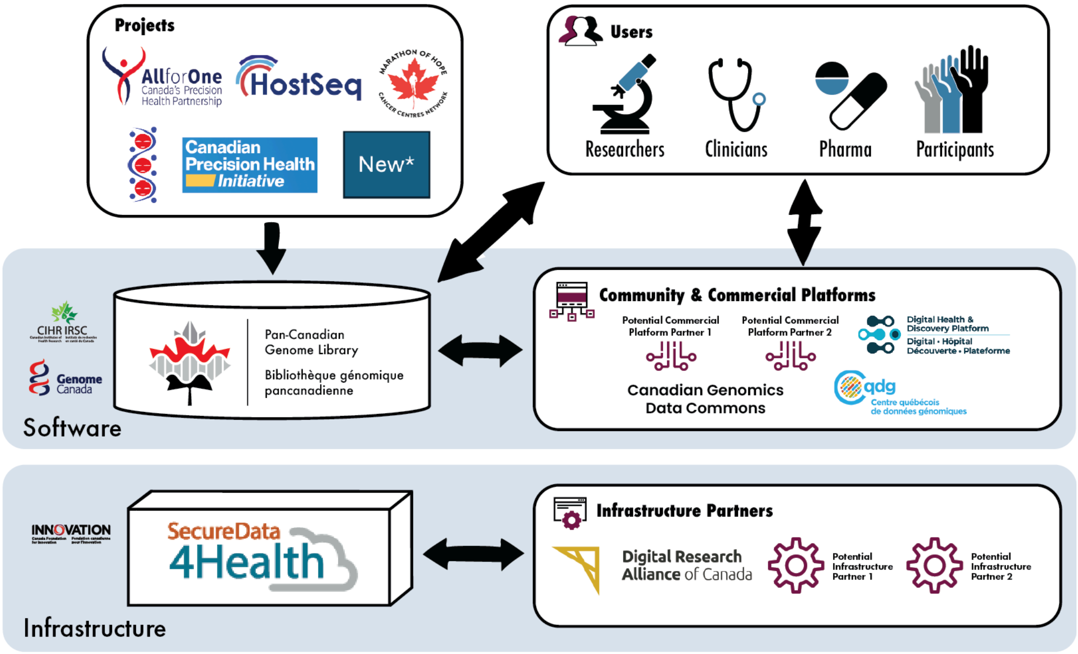

Figure 1. The PCGL Ecosystem and how it will interact with projects and users, together with infrastructure partners and community and commercial platforms.

For information about the PCGL data and application process please send an email to helpdesk@genomelibrary.ca.

3. Objectives

The objectives of the Framework are to:

- Outline benefits of partnerships with PCGL to facilitate discussions with potential partners;
- Promote a responsible attitude toward partnering with other organizations by outlining key expectations and benefits applicable to such partnerships;
- Avoid any misperception about these partnerships by the media, patients, and the public by promoting transparency through an openly accessible clear Framework;
- Contribute to the sustainability of the PCGL by providing key strategic information that will be useful to facilitate and streamline mutually beneficial arrangements with international and commercial organizations;

4. Partnership

A "Partnership" is an agreement in which parties decide to cooperate to advance their mutual interests. Organizations and businesses may partner to increase the likelihood of each achieving their mission and to amplify their respective networks.

The notion of Partnership in the Framework excludes individual users interested in accessing the PCGL data for research purposes without requiring, or providing, additional services. Those users are welcome to access our data at https://genomelibrary.ca/. Additionally, the concept of ''Partnership'' does not apply to collaboration with Canadian data producers intending on depositing their data in the PCGL. These collaborations are addressed through bilateral agreements and follow specific policies under the purview of the Working Group on Ethics, policy and regulatory compliance. However, these stakeholders may still find this Framework a useful source of information to help in their decision to collaborate with the PCGL and are encouraged to voluntarily abide by its content.

5. Core Principles

The core principles underpinning all PCGL partnerships are complementary and interdependent. They are meant to inform the applications of specific rules included in the *Framework* and to be used to help resolve any novel issues raised by PCGL partnerships that are not addressed by specific rules, standards, or guidelines. They include *Transparency, Accountability, Reciprocity, Academic Integrity, Benefit to Society, Equity, Diversity* and *Inclusion*, *Respect for Persons*, and *Open Science*.

- Transparency: A sustained commitment to honesty, integrity and openness of management structures, practices, and objectives. Respecting this principle entails full disclosure of any potential or perceived conflicts of interest involving the parties, nature and aims of the partnership.

- Accountability: Willingness to provide explanations, justifications, and, more generally, to assume responsibility for one's actions, omissions, judgments, and intentions.

- Reciprocity: The practice of exchanging materials, methods, and advantages with others for mutual benefit. Reciprocity requires a proportional distribution of the benefits and charges of the collaboration between partners.

- Academic Integrity: A commitment by the PCGL and its partner organizations to protect the freedom of researchers and students to study and conduct research without unreasonable interference or restriction from institutional regulations, contractual arrangements, or other undue pressure. Similarly, the right of scientists and students to publish their data and conclusions without control or censorship ought to be preserved. Academic Integrity also supports the recognition of the valuable contribution made by PCGL partners, and PCGL by respecting the *Acknowledgement and Publication Policy of the PCGL (TBD)*.

- Benefit to Society: This principle is an important reminder that partnerships should be established with the best interests of Canadians in mind, facilitate genomic research globally and, ultimately, improve healthcare for the benefit of future and current patients and healthcare workers. It also requires special attention to the needs of people or groups of society in situations of vulnerability.

- Equity, Diversity, and Inclusion: Equity as a guiding principle means that the PCGL will respect and value differences by actively identifying and removing barriers, to ensure that historically excluded groups have the same opportunity to fully flourish within, and benefit from, the project. Ideally, diverse communities of research participants and patients should be able to be included in, and benefit from genomic research. Furthermore, all stakeholders should benefit from equitable decision-making at every level of the PCGL from design to implementation. To promote inclusive communication, the PCGL and its partners should utilize multiple media types, such as infographics and videos, to convey tailored information to different categories of stakeholders.

- Respect for Persons: Individual patients and participants are key stakeholders, and PCGL and its partners must respect their welfare and autonomy, including by following clearly expressed preferences regarding their data. Persons with diminished autonomy are entitled to special considerations, they should be allowed to participate in the PCGL with adapted measures and oversight that respect legal and ethical standards ensuring their appropriate involvement, inclusion and protection.

- Open Science: Open science seeks to improve scientific research processes, and data utility, by promoting greater openness and transparency from stakeholders of the research ecosystem. Practically, the PCGL will foster open science by implementing the FAIR data standards and policies such as those created by the Global Alliance for Genomics and Health (GA4GH) to the extent that is permitted by law and research ethics. While open science is a major consideration for PCGL, its application may need to be tempered to account for one or more core principles.

6. Partnership Opportunities

The PCGL is highly collaborative and plans to enter in a variety of partnerships with international and commercial organizations to fulfill its objectives. Broadly defined, the following types of partnerships are of interest to PCGL:

- Public-Private Partnerships: A catch-all category, these would involve any collaboration between PCGL and private companies, such as biotech firms or pharmaceutical companies that go beyond simple access to the PCGL data (i.e., data sharing agreement).

- Industry-Sponsored Research: Private companies may be interested to fund research projects involving the use of PCGL data to discover new drug targets, develop personalized medicine, or identify genetic markers for diseases.

- Licensing Agreements: Organizations and PCGL may wish to enter in a licensing agreement to acquire or commercialize tools related to the management, FAIRness (as in FAIR principles requirement) or other aspects relating to the operation of a genomic database or, genomic research.

- Service Agreements: Organizations and PCGL may wish to enter into a service agreement to benefit from specific professional services related to the management, FAIRness (as in FAIR principles requirement) or other aspects relating to the operation of a genomic database, or genomic research.

- Database networks and consortia: These are large-scale collaborations involving databases located in multiple countries that share a common aim (ex. the International Cancer Genome Consortium). These partnerships help pool resources, expertise, and data, leading to more comprehensive and impactful research outcomes. They also address global health challenges by fostering innovation and ensuring that genomic data benefits a wide range of populations.

- Associations of projects and stakeholders: These associations involve the international cooperation of multiple stakeholders, including academic institutions, private companies, database projects and government agencies with the primary objective of advancing genomic research. To achieve this, they focus on knowledge sharing and the development of standards, policies and tools.

7. Ethical Commitment from PCGL and Partners

- Summary descriptions and aggregate statistics of PCGL datasets are available in a public database. Everyone can explore the public database or use it to make discoveries. Information from individual participants is also available, but only for researchers who are approved by the PCGL Data Access and Committee (DAC). Any direct participant identifiers, such as their name or address, are removed from the data that is made accessible to researchers. Our partner organisations are expected to always respect patient confidentiality, and not attempt to re-identify PCGL participants' data.

- All partnerships involving potentially identifying participant data are contingent on signing a *Data Access Agreement*, a *Collaboration Agreement,* or both and subject to the approval of the PCGL Data Access Committee (DAC) and the Executive Committee.

- The PCGL does not provide access to data from Indigenous patient cohorts. Instead, the PCGL may be able to assist partners in locating a project working with Indigenous participants that would meet their research needs. Partner organisations will then be responsible for contacting the project's access office directly to inquire about the possibility of using their data for their research.

- The PCGL never sells participant data that is under its oversight, nor will it seek to make intellectual property claims over such data. The PCGL may however charge an access fee to cover the cost of maintaining the portal and providing controlled access. Additional tools and services developed for the portal may also be commercialized.

- The PCGL will not enter any partnership that would effectively limit the use of PCGL datasets for the scientific community.

- All agreements concluded with the PCGL should have clear objectives, benefits, and timelines. Partnerships will be reviewed on an annual basis to ensure that they meet their objectives and deliver expected benefits to the PCGL.

- Organisations interested in partnering with PCGL must be of excellent repute (i.e. no past incidents of research misconduct or criminal convictions) and clearly formulated objectives for partnering with PCGL.

- The PCGL follows the Canadian government *National Security Guidelines for Research Partnerships* (2023), *Policy on Sensitive Technology Research and Affiliations of Concern* (2023), the

Tri-Council Policy Statement II: Ethical Conduct for Research Involving Humans (2022) and all applicable Canadian privacy regulations (federal and provincial) when making decisions on potential partnerships that would involve the sharing of personal data from research participants.

- All partnerships need to abide by the *Acknowledgement and Publication Policy of the PCGL (TBD).*

- Partner organizations should declare any existing partnerships that they have that could be in conflict, or be perceived to be in conflict, with the PCGL and its objectives. More detailed provisions on conflicts of interest can be found in the PCGL *Conflict of Interest Policy (TBD).*

- PCGL partner organizations can make press releases about the collaboration and use the name and logo of the PCGL in accordance with the *Partnership Agreement* they concluded with PCGL.

- A summary of partnerships will be published on the PCGL's public website, including aims and participating organizations.

8. Useful References

1. Global Alliance for Genomics and Health, Framework for responsible sharing of genomic and health-related data (2014)
2. OECD Principles and Guidelines for Access to Research Data from Public Funding (2007)
3. UNESCO, Declaration on the Human Genome and Human Rights (1997)
4. WHO, Guidance for human genome data collection, access, use and sharing (2024)
5. The FAIR Guiding Principles for scientific data management and stewardship (2016)
6. GO-FAIR

Revision History

Version	Date	Revisions Made
Version 1	11/01/2024	Document created.
Version 1.1	11/25/2024	Incorporated feedback from membership
Version 1.2	10/28/2025	Document approved by PCGL Oversight Board