The Legal Pitfalls of Using Human DNA and Tissue in Quebec-based Biotechnology Projects

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Authors

Eric Lavallée

Partner, Lawyer Partner, and Trademark Agent

Kiran Younas

Lawyer

Biotechnology projects rely on sensitive genetic data and biological material

Nowadays, innovation-driven companies involved in life sciences, research and biotechnology handle some of the most legally sensitive assets: human tissue, biological material and genetic data. Innovation models involving tissue engineering, biobanks or AI-based analytical technologies are now based on the transfer and use of biological data with high scientific and commercial value.

Yet, many organizations still prioritize the scientific and operational aspects of their projects without giving sufficient consideration to the legal restrictions that arise when a project involves a person's DNA or biological material.

From a business standpoint, the risk is that an organization—whether a private company or a public institution—might develop a technology, but then be unable to market that technology because it does not hold the necessary rights to use the biological material and information involved.

In Canada, and particularly in Quebec, laws that protect personal and health information have become central to such projects.[1] We are no longer simply dealing with typical cybersecurity or privacy concerns. These laws directly affect how biological material is:

- collected
- used
- transferred
- stored
- altered

and potentially leveraged for commercial or collaborative research purposes .

Why DNA and human tissue are subject to a particular legal protection

The highly sensitive nature of DNA and genetic data is no longer disputed. Canadian case law has long recognized the highly personal and private nature of this type of information.[3] It also emphasizes the fact that human tissue and genetic data play a unique role in research and innovation projects because of the identification risks they carry, their scientific value, and the ethical and commercial concerns related to their use.[4]

This perspective is evident in section 2 of the *Act respecting health and social services information*[5], for example, which defines health information as any information that concerns "any material taken from [a] person," including biological material. Section 5 and following of this act set out the conditions under which such information may be used, disclosed or transferred in the context of research or collaboration involving third parties[6]

These obligations supplement those set forth in the *Act respecting the protection of personal information in the private sector*,[7] which requires in particular that personal information be collected for specific and legitimate purposes, and that it be used in a manner consistent with the purposes for which it was originally collected.[8]

Artificial intelligence, genetic data and the risk of re-identification

From a biotechnology perspective, the matter becomes particularly touchy when human tissue or genetic data, which was initially collected for clinical or scientific purposes, is then used for technology or artificial intelligence projects. In fact, many projects that utilize artificial intelligence require not only biological samples and DNA, but also phenotypic data, health information and family history information from the patients from whom the biological samples were obtained. As such, there is a real risk of data cross-referencing here that must be managed with full awareness of the potential impact on those individuals.

In certain projects, combining DNA with family information could compromise the privacy of not only the individuals from whom the biological material was collected, but also their family members. This problem has already been raised in relation to genetic genealogy.[9]

Consent, health information and secondary uses tend to be overlooked

A project that was initially intended for research purposes can quickly drift into secondary uses that extend beyond its original scope. However, consent obtained at the outset does not necessarily cover all future uses, particularly where derived data or analysis results are integrated into technology platforms or used to develop analytical tools.[10]

Research agreements and biological material transfer agreements constitute an essential governance mechanism

Agreements have thus become the key governance mechanism. Biological material transfer agreements, collaborative research agreements and data-related provisions are no longer solely intended to protect intellectual property or commercial confidentiality. They also serve to define the processes involved in transferring biological samples, ensuring data traceability, imposing restrictions on reuse and meeting anonymization requirements.[11]

The rights relating to intellectual property, DNA and personal information are interconnected

The interplay between biotech innovation, intellectual property and personal information protection raises complex legal issues. A genetic database or a biological model derived from it can be both a

strategic business asset AND a collection of highly sensitive personal information.

However, any intellectual property rights that may apply to the results, algorithms or analytical methods do not exempt organizations from the obligations set out in Quebec laws regarding the protection of personal and health information[12]. On the contrary, in order to market a technology, organizations must hold not only the necessary intellectual property rights but also the rights required under the legal framework governing health and personal information.

The commercialization of a technology begins long before it is brought to market

As organizations increasingly seek to leverage data from scientific research, issues related to the governance of human tissue, DNA and biological material should no longer be treated as a secondary consideration addressed only at the end of a project. They are becoming an integral part of the legal, operational and commercial framework of modern biotechnology projects and therefore deserve careful consideration from the outset.

Summary

1. From a legal standpoint, DNA is considered to be health information

In Quebec, biological material and genetic data are not merely instruments of research. Under the law, they are defined as highly sensitive “health information”. The collection, use and transfer of this type of information is strictly regulated and requires explicit, informed consent.

2. Intellectual property does not confer all rights to the holder

Just because a company develops a high-performance AI algorithm or an innovative biological model does not mean it can circumvent Quebec’s privacy laws. Bringing biotech products to market requires holding the necessary intellectual property rights AND complying with the legal framework governing the use of health data.

3. The pitfall of project drift (secondary uses)

Consent obtained at the outset of a clinical research project usually does not extend to future uses, such as the integration of data into AI platforms. Organizations that fail to establish a solid contractual framework (e.g., transfer agreements, anonymization clauses) from the start may never be able to market their technology.

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1. *Act respecting health and social services information*, CQLR c R-22.1, ss. 1, 2, 5, 44 to 49 and 77.
2. *Act respecting the protection of personal information in the private sector*, CQLR c P-39.1, ss. 4, 5, 8, 12 and 14.
3. *R.* v. *Dyment*, 1988 CanLII 10 (SCC), [1988] 2 SCR 417
4. Marie Hirtle and Bartha Maria Knoppers, *Le stockage des éléments du corps humain, les droits de propriété intellectuelle et les autres droits de propriété*, Industrie Canada, 2014.
5. *Act respecting health and social services information*, supra, note 1, s. 2.
6. Id., ss. 5, 44 to 49 and 77.
7. *Act respecting the protection of personal information in the private sector*, supra, note 2.
8. Id., ss. 4, 5, 8, 12 and 14.
9. Clausius, K., Kenny, E. & Crawford, M. J. (2023). BILL S-231: The Ethics of Familial and Genetic Genealogical Searching in Criminal Investigations. Canadian Journal of Bioethics / Revue canadienne de bioéthique, 6(3-4), 44–56.
10. *Act respecting health and social services information*, supra, note 1, ss. 44 to 49; *Act respecting the protection of*

personal information in the private sector, supra, note 2, ss. 12 and 14.

11. *Act respecting health and social services information*, supra, note 1, ss. 48 and 49; *Act respecting the protection of personal information in the private sector*, supra, note 2, ss. 18.3 and 23.
12. *Act respecting health and social services information*, supra, note 1, ss. 5 and 49; *Act respecting the protection of personal information in the private sector*, supra, note 2, ss. 12, 17 and 18.3.