

**Appendix: An ethical framework for secondary uses of patient data (1) adapted to the Canadian context (2,3)**

Ethical questions	Policies and practices
<p><i>Does the data collection and data uses <b>respect patient autonomy</b>? (Respect for Autonomy)</i></p>	Inclusion of stakeholders (e.g. patients, marginalized communities) at all stages of data collection, storage and use
	Patient consent models that reflect risks and benefits of proposed data uses
	Agreements that enable Indigenous data governance and data repatriation
	Agreements that enable marginalized communities to have governance over and access to their data
<p>Is <b>public good and clear scientific value</b> the primary factor in deciding whether to permit an analysis? (<i>Beneficence</i>)</p>	Approval of data uses based on significant public benefit
	Independent data governance committee
<p>Is the data collection and data uses <b>fair, just and open</b>? (Justice)</p>	Priority placed on projects that address equity and health disparities
	Full transparency of how decisions to permit data use were reached
	Full transparency of agreements with third parties that conduct analytics
<p>Is infrastructure in place to prevent or minimize <b>individual or collective harm</b>? (Non-maleficence)</p>	Full transparency of data governance, decisions, data collection, storage, linkages, analytics and end-uses
	Public outreach and education so that the public and communities have an understanding of all processes
	Standards in place for data collection, storage, linkages, analytic methods and data uses
	Active oversight by independent governmental regulator with ability to enforce rulings and enact penalties
	Active oversight by an independent academic or governmental ethics committee

\*Adapted from the systematic review and ethical inquiry by Stockdale et al (1) and informed by principles from CARE (3), EGAP (4) and Diabetes Action Canada participatory governance model (2)

1. Stockdale J, Cassell J, Ford E. “Giving something back”: A systematic review and ethical enquiry into public views on the use of patient data for research in the United Kingdom and the Republic of Ireland. *Wellcome Open Res* [Internet]. 2019 Jan 17 [cited 2019 Sep 12];3. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6402072/>
2. Willison DJ, Trowbridge J, Greiver M, Keshavjee K, Mumford D, Sullivan F. Participatory governance over research in an academic research network: the case of Diabetes Action Canada. *BMJ Open* [Internet]. 2019 Apr 20 [cited 2020 Apr 2];9(4). Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6500288/>
3. Carroll SR, Garba I, Figueroa-Rodríguez OL, Holbrook J, Lovett R, Materechera S, et al. The CARE Principles for Indigenous Data Governance. *Data Science Journal*. 2020 Nov 4;19(1):43.
4. Black Health Equity Working Group. ENGAGEMENT, GOVERNANCE, ACCESS, AND PROTECTION (EGAP): A Data Governance Framework for Health Data Collected from Black Communities in Ontario [Internet]. 2021. Available from: [https://blackhealthequity.ca/wp-content/uploads/2021/03/Report\\_EGAP\\_framework.pdf](https://blackhealthequity.ca/wp-content/uploads/2021/03/Report_EGAP_framework.pdf)