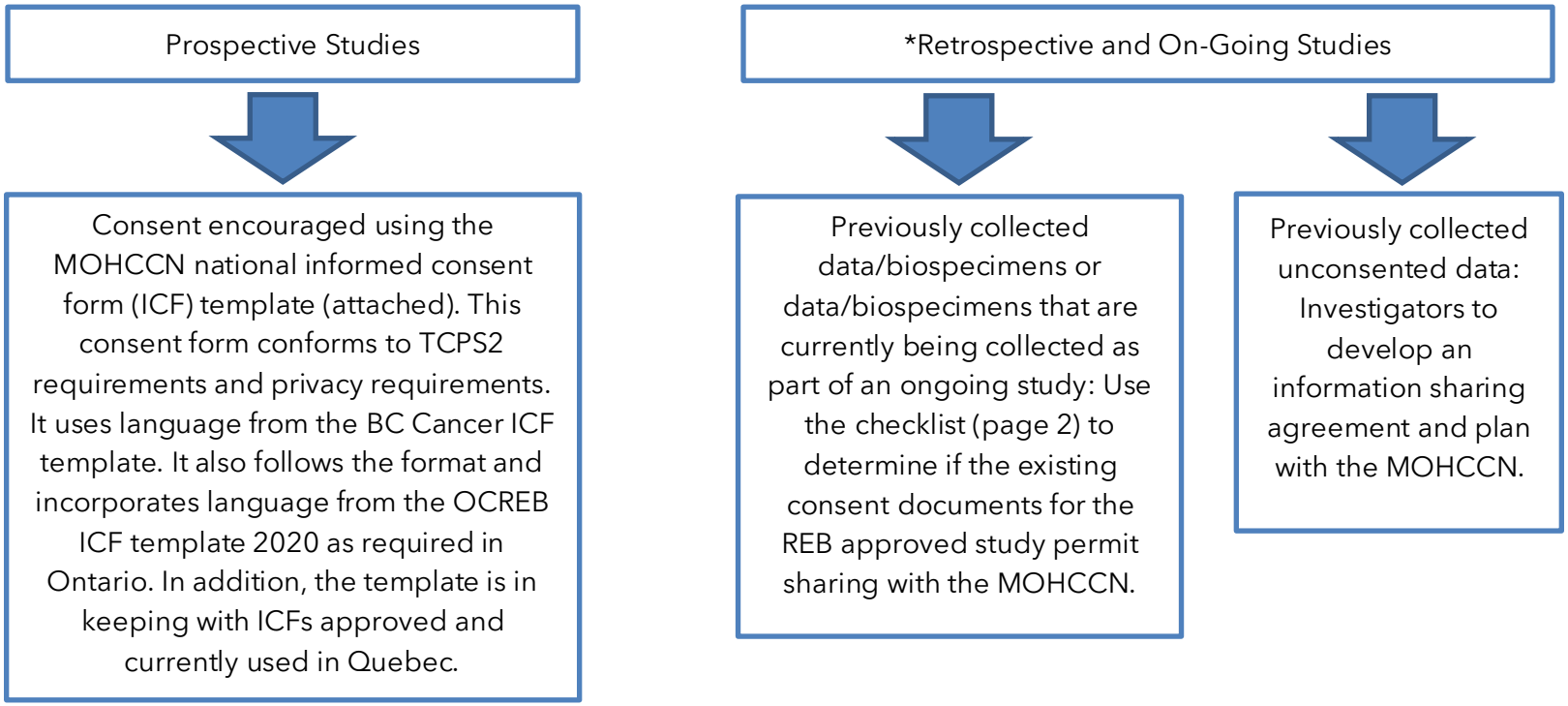
MARATHON OF HOPE CANCER CENTRES NETWORK CONSENT FORM CHECKLIST

This checklist is to guide eligibility of Marathon of Hope Cancer Centres Network (MOHCCN) study cohorts.



* Waiver of consent from the REB that complies to the waiver of consent articles in TCPS2 (chapters 5 and 12) provided the data/biospecimens were **not collected as part of an Indigenous community engaged project**, which requires different processes in Canada.

Please note that in order to receive a waiver of consent from the REB under TCPS, it is stated that it must be impossible or **impracticable** to seek consent from individuals to whom the information relates or from whom the materials were collected. This can be a very high bar for some REBs since the definition of **impracticable** according to TCPS means incapable of being put into practice due to a degree of hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience.

CONSENT FORM CHECKLIST FOR RETROSPECTIVE/ONGOING STUDIES

This is a consent checklist that can be used by retrospective/ongoing REB approved studies that wish to share data for human genomic research in Canada. It is designed as a general resource for human genomics research and data sharing, and users can adapt it to the context of the Marathon of Hope Cancer Centres Network (MOHCCN). These core elements were published as part of a guidance for policy intended for researchers who engage in, and the REBs that evaluate, human genomics research in Canada (Longstaff et al., 2022).[1] Alternatively, study teams may use information sharing agreements to contribute unconsented data. Investigators who wish to contribute such unconsented data will be required to develop agreements with the MOHCCN.

[1] Longstaff H, Flamenbaum J, Richer E, Egar J, McMaster C and Zawati M. (2022). Core elements of participant consent documents for Canadian human genomics research and the National Human Genome Library: guidance for policy. *CMAJ*. November 15, 2022 194 (44) E1500-E1508; DOI: https://doi.org/10.1503/cmaj.212063

Table 1: Recommendations for core elements for participant consent documents used in human genomics research in Canada

Core consent elements*	Example of consent clause language*
Research data	
Participants should be given a full description of the type of data collected for research, including whole genome or exome sequencing of the sample and the ongoing collection of clinical data from participants' medical records or charts, administrative databases, etc.	*You are being invited to participate and asked to give consent for the whole genome or exome sequencing of the DNA from your sample and for access to your genetic data by the pan-Canadian Human Genome Library, to be used for research purposes. You are also being asked to provide clinical data that includes some personal information, such as your age, ethnicity and family's health history.* *If you agree, we will also request health information about you from your family health care provider or health care provider of choice and from other institutions or registries that may have your health information; for example, [where applicable, include any relevant governmental or administrative health data repository]. We may get coded research data from other studies that you were involved in, including future studies.*
International sharing	
It should be made clear to the participant that there will be international sharing of genetic and clinical data.	*The Canadian Human Genome Library will share your genetic and clinical data with researchers that it has approved.* *Researchers around the world – who may include researchers from academia, charitable organizations, hospitals and for-profit companies, such as drug companies – may request access to your coded data, overseen by a strict access governance process that includes patient and community participation.*
Future research use	
Consent forms should include an explanation that future health research will be conducted with participants' data on a range of health outcomes that are unknown at this time.	*Your coded stored genetic and clinical data will be accessible through the Canadian Human Genome Library for future research on what makes you sick and keeps you healthy.*
Commercial use	
It should be made clear in the consent that genetic and clinical data will be used for commercial purposes.	*It is possible that future research using your data will eventually lead to the development of new diagnostic tests, new drugs or other commercial products. If this happens, you will not receive any share of profits or compensation.*

Core consent elements*	Example of consent clause language*
Controlled access	
Participants should be told that the sharing of genetic and clinical data will be conducted through a controlled-access mechanism.	*Your coded data will be accessible only to researchers approved by the Canadian Human Genome Library, after review by its access committee. The access committee will verify, among other criteria, that the proposed research use conforms with the objectives of the Canadian Human Genome Library, and that the research team applying for access has obtained the proper research ethics approval (if applicable).* *Approved researchers will sign agreements. These agreements will control how the data will be used. The access committee will also determine not only who will have access to the data, but also when, in what format and for what specific use.*
Location of storage	
Participants should be told that genetic and clinical data in the library will be stored on centralized servers in Canada.	*Data in the Canadian Human Genome Library are under the responsibility of a Canadian, federally funded national group and are made accessible through a platform for genome sequencing and analysis. Data accessible through the Canadian Human Genome Library are stored on servers located in Canada, including cloud-based servers.*
Duration of storage	
Consent forms should explain that genetic and clinical data will be stored indefinitely.	*The data stored in the Canadian Human Genome Library will be kept until they are no longer useful for research or as required by law.*
Data withdrawal	
Participants should be told that it will not be possible to withdraw data that have already been distributed and used.	*If you decide to withdraw from the Canadian Human Genome Library, your data will no longer be shared, and no new data will be collected.* *If you decide to withdraw, your data stored in the library will no longer be accessible by the library as of the time of your notification. However, it may be impossible to withdraw your data once they have been processed and shared with other researchers. In these cases of total withdrawal being impossible, your identity will continue to be protected.*
Reidentification	
Consent forms should explain that there is a low risk that the participant could be reidentified in the future.	*There is always a small risk that your data may be used to reidentify you. Genetic information is unique to every person, just like a fingerprint. This means it is possible that you can be identified by your genetic code. However, this is not easy to do. As technology*

Core consent elements*	Example of consent clause language*
	advances, there may be new ways of linking data back to you that we cannot foresee today, despite the strict security measures. The potential reidentification or unintentional release of your genetic and clinical research data could lead to loss of privacy for you or your biological relatives.
Recontact (includes mature minors)	
Consent forms should include an option for recontact of participants. Although not mandatory, it is recommended that, where applicable, mature minors be included in the consent process and given the option for recontact as well.	*I understand that the data I provide will be used for many different research studies in the future. Rarely, recontact may be necessary in some cases (e.g., if additional information is required).*
Assent	
There should be an option for obtaining assent of children, where applicable.	*If you decide you want to be in this library, please print or write your name. If you decide that you don't want to be in it, then all you have to do is tell me [insert name].* Note: The assent of a minor, capable of understanding the nature of the research, could be indicated with a signature (which could be electronic) or printed name, or by obtaining verbal assent.

- The examples and explanations are tailored for the Canadian Human Genome Library (CHGL). The wording may vary depending on the requirements of other research projects.

Table 2: Additional considerations* for human genome research consent documents

Topic	Description‡
Any limitations on consent for open data sharing and extent of those limitations	The guideline text is based largely on the accepted concepts of open data sharing, guided by the FAIR principles.[2] For the Canadian Human Genome Library, sensitive data will be accessed through a controlled-access system. However, the working group is aware that some potential research participants, for various reasons, may not be willing to consent to open data sharing, even for nonsensitive data sharing. Mechanisms to allow data sharing with agreed-upon governance for Indigenous people, or others with similar concerns, may result in more inclusive opportunities. For example, the Global Indigenous Data Alliance,[3] supporting international Indigenous Sovereignty, has enhanced the FAIR principles with the CARE principles (Collective Benefit, Authority to Control, Responsibility and Ethics) and OCAP (ownership, control, access and possession).[4]
Processes for the management and return of material incidental findings	Researchers have the obligation to return findings if they are material (analytically valid, clinically significant and actionable) and if participants have opted in to receiving them.[5] Exceptions include when return is impractical or impossible.
Clarifying purpose and distinguishing between individual, societal and other benefits of research participation	Research is intended to produce societal benefits and to not benefit participants directly, although this may change over time. The results could become available, but this may be years in the future, if at all.
The collection, use and disclosure of personal identifiers	Researchers may be required to list any personal identifiers that will be necessary to collect for data linking purposes, such as a personal health number, and any unique identifiers that will need to be produced by the CHGL to follow participants over time.
The need to access biospecimens	The CHGL will not host a biobank. However, individual research projects may need to access or transfer biospecimens in order to validate results from these studies or use analytic tools or innovations that may not be available to all CHGL-accredited researchers. These biospecimens may have been collected as part of clinical care or participation in a research study. If access is necessary, researchers may be asked to clarify how they will follow the storage, sharing and destruction requirements that govern biospecimens kept at a local site. Biospecimens should typically be coded before leaving any local site. They will be shared with CHGL-approved researchers and their collaborators, which may include commercial collaborators.

[2] Wilkinson MD, Dumontier M, Aalbersberg IJ, et al. The FAIR Guiding Principles for scientific data management and stewardship. Sci Data 2016;3:160018.Google Scholar
[3] GIDA: Global Indigenous Data Alliance [homepage]. Available: https://www.gida-global.org (accessed 2022 June 20).
[4] The First Nations Principles of OCAP. Akwesasne (ON): First Nations Information Governance Centre. Available: https://fnigc.ca/ocap-training/ (accessed 2022 June 20).
[5] Green RC, Berg JS, Grody WW, et al. ACMG recommendations for reporting of incidental findings in clinical exome and genome sequencing. Genet Med 2013;15:565–74.

Topic	Description‡
The need to access administrative data	Health Data Research Network Canada has prepared a resource[6] for researchers on informed consent wording for linking to administrative data across Canada. This wording can be included in consent forms to ensure that administrative data can be shared with these studies.

- Note: CHGL = Canadian Human Genome Library, FAIR = findable, accessible, interoperable and reusable data.
- ↵* These will depend on the governance of the project and technical structure of the platform used.
- ↵† The included descriptions are tailored to the CHGL.

[6] Guidelines: informed consent wording for administrative data linking. Vancouver: Health Data Research Network Canada; 2021. Available: https://www.hdrn.ca/sites/default/files/2021-05/Administrative%20Data%20Linking%20Consent%20Wording%20Tool%20V1.0_20210507.pdf (accessed 2022 June 20)