Genomic consent: New guideline to help researchers and patients

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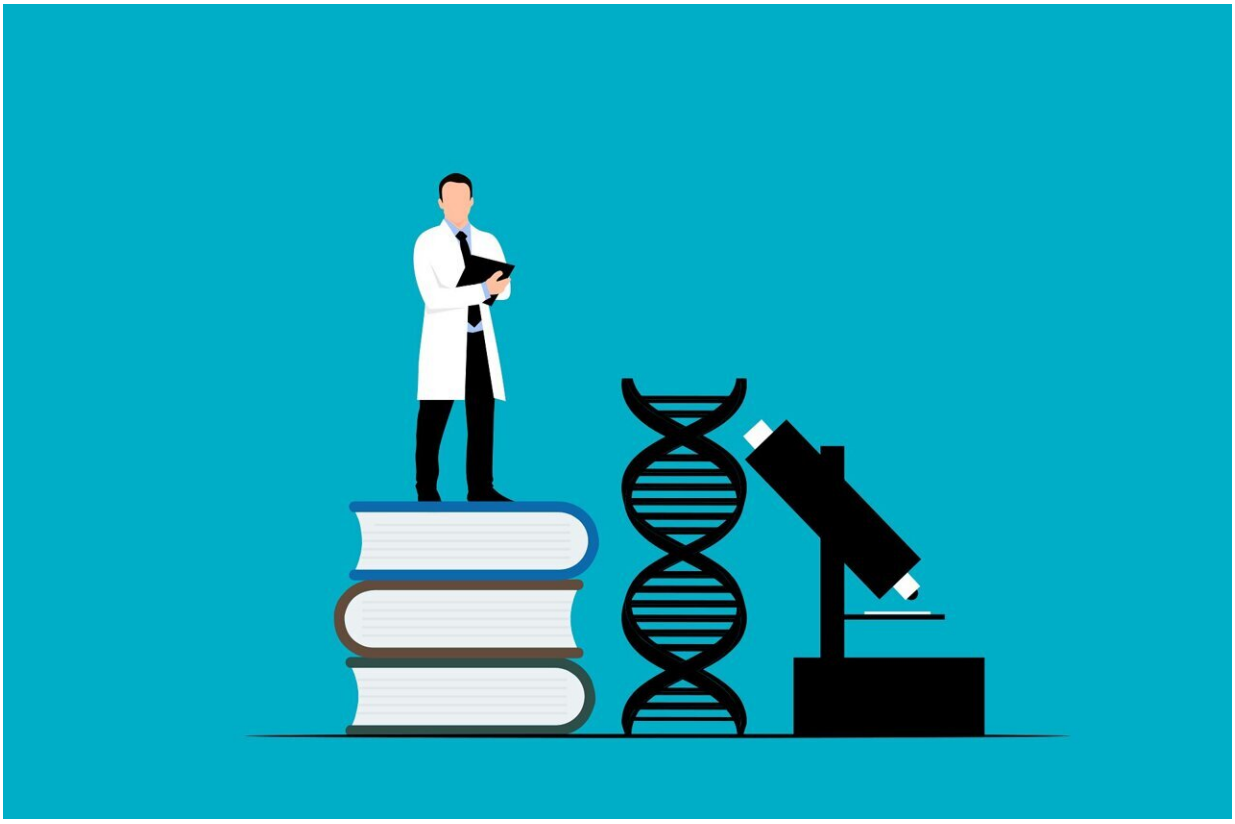

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How can Canada optimize the impact of human genomic sequencing to increase our understanding of disease? New guidance in *Canadian Medical Association Journal (CMAJ)* lays out the key elements for

obtaining patient consent for researchers and policymakers in this growing field.

"Human genomics—the study of the entirety of a person's or population's genes—is increasingly being integrated into research and rapidly incorporated into clinical care, including into health records," writes Dr. Christopher McMaster, a guideline author and Director of the Institute of Genetics, Canadian Institutes of Health Research (CIHR).

"If most genomic data obtained in Canada could be accessed and analyzed collectively, the level of understanding of the role of genomics in determining health and predisposition to disease among Canadians would increase substantially."

In 2023, a pan-Canadian Human Genome Library (CHGL) will launch as a central resource to share locally held genomic and related health and medical information. Advanced artificial intelligence and machine learning methods can be used to determine which genetic factors contribute to health and disease for people in Canada.

"Consent is an essential, required tool to enable personalized medicine for Canadians," says Dr. McMaster.

To ensure success of the library, a standardized set of core consent elements for human genomics research in Canada is needed to help with appropriate research ethics board (REB) approvals and subsequent sharing of genomic and health data. The guideline addresses topics such as research data, international sharing, commercial and future research use, storage, controlled access, reidentification and recontact of participants, and consent of minor participants.

"Genomic consent core elements will help with transparency for participants in research," says Dr. McMaster. "This guidance will allow

researchers to collect human genome data in a consistent manner that explains how participants' data will be used in the present and future."

It will also streamline REB submissions and approvals, an important part of the research process.

"This guidance will make it easier for clinicians and researchers to determine the essential core elements to put in their REB submissions," says Dr. Etienne Richer, a guideline co-author and Associate Scientific Director, CIHR Institute of Genetics.

"For REBs, it will be clearer what minimal elements to look for when reviewing submissions with genomic components. In the end, we hope that this will accelerate and make the whole process smoother for the benefit of patients and people living in Canada."

In a related commentary, Dr. Mackenzie Graham, Wellcome Centre for Ethics and Humanities, University of Oxford, Oxford, United Kingdom, writes, "Although securing informed consent remains an important facet of ethical research, the complexity and uncertainty inherent in current data-driven research means that much of how people's data are used is outside of their direct control. Participants ought to be able to make an informed judgment about whether an institution is trustworthy before they trust it with their health data."

More information: Core elements of participant consent documents for Canadian human genomics research and the National Human Genome Library: guidance for policy, *Canadian Medical Association Journal* (2022). DOI: 10.1503/cmaj.212063

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