2017 Personal Health Information Act (PHIA)

Review - Submission to PHIA Review Board

Preface - Sequence Bio is planning to conduct research in Newfoundland and Labrador, and doing so in an ethical and transparent way is our first priority. Our efforts require approval by the Health Research Ethics Board (HREB). The words "believe," "expect," "anticipate," and similar expressions, among others, generally identify our intent and/or objective to undertake research in this province and may be subject to change after HREB Review.

Introduction

Sequence Bio has the ambitious goal to launch the 100k Genome Project, a community-based initiative enabling innovative science in Newfoundland and Labrador. We intend to do this with the hope that we will have lasting, positive impacts on our healthcare system and provide overall benefits for the people of this province and patients worldwide.

Overall, our future research model is based on explicit consent from participants who wish to get involved. They will give permission (informed consent) to share a biological sample, from which genetic information will be derived, as well as other health-related information. This will then be compiled by Sequence Bio in a secure data environment in order to conduct large scale analytics.

After HREB approval has been granted, we anticipate participants will consent to share personal health information (PHI) directly to Sequence Bio, as well give permission for Sequence Bio to collect their PHI from other data sources, such as eHealth systems held by the Newfoundland and Labrador Centre for Health Information. Data collected from secondary sources will require a secure transfer of PHI from custodians across Newfoundland and Labrador to Sequence Bio. As well, we expect under the leadership from Health Research Ethics Board (HREB) to determine appropriate genetic results that we may return to participants after the biological samples have been analyzed. Herein lies the regulatory complexity that we wish to address in this submission.

Sequence Bio believes that personal health information that is collected, used and disclosed by commercial entities should be afforded the opportunity to abide by consistent rules as other health information custodians in this province. In order to foster trust and ultimately ensure consistent oversight, we believe that private commercial entities, in collaboration with custodians, should have the opportunity to opt-in to OIPC oversight and formalize a mechanism to align with PHIA in relation to our collection, use and disclosure of PHI in this province.

Stronger and more lucid privacy protections are needed for personal health information used for innovative research

Across Canada, the health research paradigm is shifting. Where historically clinical care and research were distinct from each other, the emerging trend particularly with genomics is for interconnectedness regarding diagnosis and treatment.

Undoubtedly, advancing genomics research is a massive undertaking that requires collaboration – one that many argue cannot be tackled by the public sector alone. Yet, for a public-private partnership to thrive, the statutory and regulatory regime surrounding information-sharing must keep pace; it must be flexible enough to support innovative approaches to both healthcare and research.

In essence, an effective regime must reflect the new reality of public-private partnerships. This new reality includes the need for PHI to smoothly flow both ways between custodian and researcher for iterative analysis. It means that PHI being disclosed to a researcher needs to flow in a manner that spans beyond traditional approaches. These are all byproducts of the emerging paradigm, and we should not be fearful of their attendant risks. Rather, any perceived risks should be mitigated by appropriate oversight and tailored regulatory treatment to increase the accountability of all involved.

As an example of an existing regulatory hurdle to effective partnerships, Sequence Bio is not currently a custodian listed under the *Personal Health Information Act* (PHIA). Therefore, there is no direct oversight by the Office of the Information and Privacy Commissioner (NL). Although we are contractually bound in certain circumstances to comply with PHIA, it has often led to a perception by custodians that the burden of risk for non-compliance is not adequately allocated.

Instead Sequence Bio falls under *Personal Information Protection and Electronic Documents Act* (PIPEDA), which has Federal oversight by the Office of the Privacy Commissioner of Canada (OPC). PHIA has been deemed "substantially similar" to PIPEDA[1], which employs consistent rules and aligns with the 10 Internationally recognized privacy principles. Despite being governed by PIPEDA, Sequence Bio submits that this 5-year review is a perfect

[1] http://laws-lois.justice.gc.ca/eng/regulations/SI-2012-72/page-1.html

opportunity to amend PHIA to more directly address permissible information-sharing in a comprehensive electronic health environment.

Proposed Approach

Sequence Bio is committed to working with provincial health authorities and custodians, along with the Office of the Information and Privacy Commissioner (OIPC), the Department of Health and Community Services, and others, to develop an efficient and effective ethical framework for information-sharing of personal health information required for research purposes. We want to do so in an environment where the regulatory environment is supportive of such public-private relationships and collaborations.

Sequence Bio expects to be conducting health-related research in the future once ethics approval has been obtained. At that time, it will consider itself a steward of personal health information. Accordingly, Sequence Bio wishes to be part of a principled, fully-integrated and seamless solution that would require a small amendment to PHIA that fosters a culture of meaningful information-sharing while fully embracing the need to adequately safeguard sensitive health information.

This submission seeks to address this balance by focusing on the role of the OIPC. In particular, Sequence submits that the OIPC should maintain supervisory and/or oversight powers when a custodian under PHIA shares personal health information with a non-custodian researcher (whether an individual, commercial entity or an organization) for health-related research purposes. PHIA was adopted in the province, in part, to avoid the gaps that existed because of the different legal treatment of health information between the public and private sectors. One gap remains that can be readily fixed. Currently, when personal health information is shared by a custodian to a researcher who is not itself a custodian or fall under a institution that is a custodian, the personal health information is no longer protected by PHIA.

Custodians in Newfoundland and Labrador may be uncomfortable with the notion of disclosing personal health information to outside researchers under PHIA's existing regime. Yet, our province cannot successfully develop an innovative culture around health research without custodians first being comfortable with – and understanding the statutory and regulatory processes for – sharing/disclosing personal health information with researchers and understanding the protections that will follow the information.

Part of custodians' ongoing discomfort and uncertainty may stem from the fact that the

OIPC's jurisdiction in this area (and consequently the application of PHIA) does not follow the information and abruptly terminates at the researcher's doorstep. Amending PHIA to clearly provide the OIPC with jurisdiction to oversee information-sharing or data use agreements would promote custodians' confidence in the information-sharing process and reduce PHIA compliance concerns.

Without confidence that researchers are subject to the same rules as the original custodians, those custodians are likely to hesitate to share information with those who they perceive to be outside the "circle of trust" – even when disclosing personal health information to committed data stewards, such as Sequence Bio, who implement and maintain robust security protocols to protect information.

Sequence Bio is acutely aware that more expansive jurisdiction for the OIPC will attract greater regulatory scrutiny over Sequence Bio's activities and information management processes. However, Sequence Bio submits that such regulatory oversight is an appropriate framework for meaningful information-sharing and would bolster privacy protection for personal health information used in research – whether the research is taking place within public or private entities. Any research or analytics performed on collected personal health information should be (1) transparent and (2) respectful of PHIA's overarching objective to safeguard personal health information.

In essence, the OIPC should continue to have jurisdiction over the personal health information after a custodian has transferred it to a private researcher.

We believe that section 44 of PHIA can be a starting point for amendments. There is room for the "disclosure for research purposes" scheme, perhaps by regulation, to better elucidate the essential conditions that must be attached to any disclosure. Although Sequence believes it is premature to suggest precise statutory wording, an amended statutory provision could, among other things, permit a custodian to disclose personal health information, as approved by the HREA, subject to a written agreement approved by the OIPC.

Once approval has been sought and obtained, the OIPC would have jurisdiction to investigate any alleged breach of the agreement in the same manner as the OIPC can investigate all other breaches of PHIA. This would be an optional procedure, but once a health researcher has "opted-in", their use of the personal health information remains subject to PHIA.

The approach we are suggesting is creative, but not entirely novel. Ontario's personal health

information law similarly sets out a framework that allows information-sharing with non-custodian researchers. It very specifically sets out prescribed requirements for custodians to follow respecting the execution of a data sharing agreement, creation of a research plan, and approval of the health research ethics authority. However, it suffers from a serious flaw: it was drafted in the context of the traditional paradigm, where research was siloed from client care. As such, we do not recommend adopting Ontario's framework wholesale, but instead use it as a frame of reference for more nuanced amendments to section 44.

Although we believe that using Ontario's model as a framework would be a good starting point, our suggested modification to voluntarily "opt-in" to OIPC jurisdiction would preserve requisite flexibility for all parties. Such a modification: (1) avoids the rigid, one-size-fits-all nature of the Ontario model; (2) better reflects the new paradigm of public-private partnerships; and (3) contemplates the various mechanisms and approaches available to researchers and custodians when sharing data for research purposes.

Importantly, Sequence submits that an expanded mandate for the OIPC should not interfere with, or diminish, the existing role of the HREA. On the contrary, PHIA's research provisions should continue to require the involvement, approvals, and expertise of the HREA, while providing specific access and privacy oversight in the context of health research. That aspect of the regime should remain unaffected – the OIPC's expanded mandate would simply complement the HREA and HREB's role in ensuring ethical health research in the province by filling the gaps in the legislative scheme related to privacy protection. We are of the view that this is consistent with the overall rationale for PHIA.

Next Steps

As indicated, Sequence Bio believes that personal health information that is collected, used and disclosed by commercial entities should be afforded the opportunity to abide by consistent rules as other health information custodians in this province. In order to foster trust and ultimately ensure consistent oversight, we believe that private commercial entities, in collaboration with custodians, should have the opportunity to opt-in to OIPC oversight and formalize a mechanism to align with PHIA in relation to our collection, use and disclosure of activities of PHI in this province.

All stakeholders in this process are striving to reform healthcare in this province in the most successful and innovative way possible. If we expect to accomplish this goal, we must embrace public-private partnership by meaningfully empowering it. Accordingly, the

regulatory environment that non-custodian researchers find themselves must promote such opportunities. To do so, we must focus on greater cohesion and clearer rules for oversight regarding information-sharing.

Most importantly, the result of these amendments will be in the best interests of the people of Newfoundland and Labrador, not just companies like Sequence Bio. A voluntary oversight mechanism that fosters public-private partnership on one hand, while ensuring adequate privacy protection on the other, will encourage research innovations that improve the overall quality of healthcare in the province, to the benefit of all.

We look forward to discussing this particular opportunity, as well as any other opportunities that we have not identified for health research in this province, with the PHIA Review Board in greater detail.

Sincerely,

Angela Power
Executive Director, Ethics and Privacy
+1.709.693.2464
angela @sequencebio

Prepared in collaboration with David Fraser & Trent Skanes of McInnes Cooper