NEWFOUNDLAND AND LABRADOR
HREB
HEALTH RESEARCH ETHICS BOARD

Personal Health Information Act (PHIA) Review

3rd Round Submission

Thank you for the opportunity to submit a supplementary submission to the Personal Health Information Act (PHIA) review committee as part of the statutory review of PHIA. Similar to the HREB's first submission, the comments below are limited to the context of personal health information collected, used or disclosed for health research purposes.

Policy Development and Education

The HREB supports the OIPC's recommendation that the PHIA review committee consider recommending specific areas for policy development and education, even in areas where no amendment to PHIA is ultimately proposed.

'Personal Health Information'

The HREB supports NLCHI's recommendation of the inclusion of genetic information in the definition of personal health information.

The HREB acknowledges Eastern Health's recommendation that health research be included in the definition of personal health information. More accurately, the request should be that personal health information, collected for the purposes of health research, should be included in the definition. The PHIA review committee should evaluate whether personal health information collected for research purposes is covered under the current definition, and if not, whether this would be appropriate.

'Research'

The HREB wants to reiterate comments from our first submission re: the differences between the definition of research in PHIA and the HREA Act. We reiterate concerns in certain areas; specifically, non-health research, research and non-research activities that are either not part of the review mandate of the HREB or are exempt from REB review under TCPS2, respectively. The PHIA review committee should consider reviewing the definition of research in PHIA to evaluate the implications of inconsistent definitions. While this may not result in legislative change, thought should be given to the gaps that may exist with the practical application of these two definitions.

S.44

The HREB supports NLCHI's recommendation of expanding section 44 to include specific parameters for disclosure of personal health information for research purposes. This recommendation further supports the HREB's comments in our first submission.

'Circle of Care'

The NLMA (and several other submissions) made recommendations related to the circle of care. This was something that was not part of the HREB's initial submission; however, we have noted inconsistent interpretations and application of the circle of care among custodians and non-custodians that has impacted the ability to conduct research (circle of care is important for the identification, recruitment and consent process for research that relies on patient populations). The NLMA recommended that the definition of the circle of care should be clarified and that a consistent interpretation and use of the term be communicated to all custodians and their employees. The HREB supports this recommendation.

The OIPC's supplementary submission offered their services to review draft policies and procedures of custodians to help ensure that they remain consistent with the language in PHIA. While legislative amendment may not be required, it is apparent that education would help to resolve this issue.

PHIA Compliance

The HREB supports the exploration of the various recommendations put forth by the OPIC to better PHIA compliance. One recommendation was that the Commissioner have authority to conduct audits to determine PHIA compliance, particularly for smaller independent custodians. Another recommendation was making certain elements of PHIA compliance mandatory in order for health professionals to maintain their registration with their professional colleges or boards. The protection of personal health information in the context of health research is a fundamental element in the protection of research participants' rights. It is critical that compliance is consistent, and robust, across all custodians involved in health research.

'Custodian'

Section C.3.1. of Eastern Health's submission indicated that there is ambiguity with the application of the term 'custodian' with respect to secondary uses of data. We agree that clarity is required. This comment further supports the HREB's submission that described confusion in this area for requesting access to personal health information for secondary purposes (i.e. health research).

The HREB shares concerns associated with custodians disclosing personal health information to non-custodians for research purposes. We agree with the OIPC supplementary submission that the committee needs to be aware of this concern and make recommendations to remedy it.

The HREB supports Eastern Health's recommendation that the definition of custodian should include all faculties and schools of post-secondary institutions who are involved in health research. In the absence of an equivalent privacy framework that would govern the personal health information obtained for research purposes at these institutions, the HREB agrees that PHIA should apply to mitigate a number of negative outcomes. Bearing in mind that a large proportion of health research is conducted by MUN researchers, and a portion of this research relies on accessing data without consent of participants, there are serious privacy concerns that would go unaddressed if MUN was not required to be PHIA compliant. Without any oversight of this personal health information, the HREB cannot assure research participants that their information is being used appropriately, and ensuring their rights as research participants are being protected.

The HREB disagrees with MUN's position that the application of PHIA to research data and MUN's researchers unnecessarily duplicates the legislative requirements of PHIA and the HREA Act, and the existing ethical requirements imposed by the Tri-Council Funding Agencies. The HREB's initial submission described the limits of the HREA Act, and the role of the HREB and how the research ethics review process relies on the corresponding research review process (i.e. organizational review process) whereby organizations/data custodians evaluate the approved research in the context of their responsibilities under applicable legislation. The HREB continues to hold this position.

The HREB agrees with the OIPC's analysis of EH, MUN and HREB's first round submissions and how it relates to MUN's proposal of being delisted as a custodian, particularly that "the submissions of NLCHI, EH and HREB, clearly demonstrate that the statutory regime that exists currently is not a barrier to research, but instead is an asset which supports research by providing the assurance of clear legislated accountability". The HREB would like to reiterate a point from our initial submission that is critical to this discussion – the HREB is a provincial REB that is external to all organizations/data custodians in the province. The HREB's mandate is to review the ethical acceptability of research, as such; the research

ethics review process relies on the corresponding research review process (i.e. organizational review process) whereby organizations/data custodians evaluate the approved research in the context of their responsibilities under applicable legislation. If MUN delisted its schools/faculties as custodians under PHIA, there would be significant negative impacts on researchers and their ability to acquire data for health research.

The HREB also disagrees with MUN's position that "continuing to include the faculties in the definition, and continuing to impose PHIA on MUN creates many potential problems within the research context". Given that these claims were not substantiated in MUN's submission, the HREB is not in a position to comment beyond the points already raised which demonstrates the opposite.

PIA

The HREB supports in general the OIPC's recommendation that large custodians (e.g. Department of Health and Community Services, RHAs, MUN) must complete a PIA for all proposed new administrative practices and information systems or proposed upgrades/changes to existing practices and systems that relate to the collection, use, disclosure and storage of identifying health information (or information that could be re-identified).

There was a further recommendation by the OIPC that this requirement would not apply to MUN for research projects approved by an REB. An example was given that the establishment of a research database at MUN would require a PIA; however, the creation of a research database would require review by an REB. The HREB feels that this recommendation should apply to all large custodians, not just MUN. Also, the HREB agrees that the wording of a new PIA provision in PHIA should be clear and consistent.

Private Sector

The HREB agrees with the various comments/recommendations related to effective oversight of privacy protection laws for the private sector, particularly in the area of genetic research. The HREB agrees that the fundamental concern is that personal health information will not be misused or removed from the regulatory oversight of this jurisdiction. The HREB agrees that it is critical that government consider appropriate action to mitigate risks to data collected by the private sector. The OIPC's suggestion of adopting something similar to section 54 of Alberta's *Health Information Act* (requiring custodians and researchers to enter into an agreement before the custodian is allowed to disclose the information) would be helpful in the NL setting, particularly as our provincial HREB is external to any institution. This supports the HREBs initial submission where it described the limits of the HREB's review/mandate and how it relies on custodians fulfilling their mandate under PHIA. A model where agreements are required for the custodian prior to releasing data would strengthen this process.

The HREB feels that very important concerns have been raised in the various first round submissions and look forward to continued discussion in this area.

Registries

The HREB supports NLCHI's recommendation that the PHIA Review Committee consider adding details within the PHIA or PHIA Regulations around the requirements of establishing, and maintaining a registry. The OIPC's supplementary submission outlined concerns re: the operation of current registries without being formally designated by regulation under PHIA. This is of particular concern as personal health

information being disclosed without consent into a registry, which may later be accessed for research purposes, may not be approved by an REB if a justification for a waiver of consent cannot be made. Without this being carefully reviewed, there may be limited use of the data in these registries for future research.

Conclusion

Looking globally at the submissions that formed the basis of the PHIA review process, it appears that the main theme arising is a need for equivalency and consistency in the protection of personal health information in the province. This would include equal application of the provisions of PHIA to those who collect, use, disclose and retain personal health information, and consistency in PHIA application and compliance for all those who are bound by it. The HREB supports the recommendations submitted that support this concept and warn against any submissions that may create fragmentation in the regulatory environment.