Disclosure of Personal Health Information for Research Purposes: Guidance for Researchers and Custodians of Personal Health Information

The legal framework surrounding the disclosure of personal health information for research purposes is multi-faceted, and compliance with it is crucial in order to preserve and protect public trust in all health research efforts undertaken in the Province. A common understanding amongst stakeholders as to their respective duties to protect privacy is therefore essential. That understanding must be informed by legislative obligations to protect the privacy of research subjects' personal health information. Some key obligations are addressed below.

The *Health Research Ethics Authority Act* (*HREAA*) and the *Personal Health Information Act* (*PHIA*) address obligations of the Health Research Ethics Authority (HREA), custodians and researchers.

The HREA is empowered to ensure that health research involving human subjects is conducted in an ethical manner. This is achieved primarily via the requirement that all research in the Province involving human subjects be reviewed and approved by a Research Ethics Board (REB) established under the *HREAA*.

Although ethics approval by a REB takes privacy considerations into account, *PHIA* governs the privacy of personal health information and imposes legal duties on researchers and custodians. Researchers and custodians must understand that HREA approval does not relieve them from their *PHIA* obligations related to the collection, use and disclosure of personal health information.

Collecting and Disclosing Personal Health Information

There are two ways for a researcher to collect or access personal health information under *PHIA*.

Under section 44, a custodian of personal health information ***may*** disclose personal health information to a researcher ***without*** the consent of the individual, but ***only*** where the disclosure has been approved as part of a research project by the REB.

Secondly, personal health information may also be collected by researchers through the ***consent*** of research subjects, however even with consent, approval from the REB is required. Where consent is provided, the same privacy principles and expectations apply to the project for example, the collection of the minimum amount of information necessary for the identified purpose. Whether one or the other approach is used, or a combination of the two, researchers and custodians need to be aware of their legal duty to protect the privacy of research subjects' personal health information.

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Consent

Section 23 of *PHIA* requires that consent be:

- of the individual;
- knowledgeable; and,
- not obtained through deception and coercion.

For consent to be considered knowledgeable, *PHIA* requires that it be reasonable in the circumstances to believe that the individual knows:

- the purpose of the collection, use or disclosure;
- that he or she may give or withhold consent; and
- that the information may only be collected, used or disclosed without consent in accordance with the *Act* (for the purpose of conducting research, this means that if it is not collected through consent, it must be collected in accordance with section 44).

The Office of the Information and Privacy Commissioner (OIPC) will consider consent to be knowledgeable (as defined in *PHIA)* only if the sources of personal health information are explicitly stated in the consent form and REB documentation. Details must also be provided as to how the information is being collected (directly or indirectly). Consent that does not comply with *PHIA* requirements may result in the researcher and his or her employer (if the employer is a custodian under *PHIA*) being audited or investigated. Willful breaches could result in prosecution under *PHIA*.

Researchers

- Researchers must be explicit and identify in detail in an application to the REB the specific information they intend to access (or collect) from the custodian and/or the specific information they intend to collect directly from participants as part of the research project.

- Researchers who access or attempt to access personal health information beyond what has been explicitly approved by the REB are accountable under *PHIA* and to the REB. Employers of researchers may also be held accountable if the research occurs in the course of employment by a custodian, such as a regional health authority, the Centre for Health Information, or the Faculty of Medicine at Memorial University.

- Approval by the REB is only one step. Custodians are accountable under *PHIA* when they permit access to the personal health information of patients. As such, researchers should expect to have their REB approval documents reviewed by the custodian and be prepared that the custodian may have additional questions and/or place additional requirements or restrictions on the project in order to ensure that the minimum amount of personal information is collected for the project, that it is accessed within the boundaries set by the custodian and that it is stored securely, etc. When a custodian discloses information to a researcher, it does not transfer

"ownership" of the data and researchers should anticipate that the custodian will establish expectations regarding retention, destruction and future use, among other things.

- If the scope of a research project changes after REB approval has been granted, it is the responsibility of the researcher to return to the REB to seek an amendment. Researchers need to update custodians if additional or expanded access to personal health information is required beyond that previously approved by the custodian.

Custodians

- In accordance with section 44 of *PHIA*, a custodian of personal health information may only disclose personal health information to a researcher where the information has been approved by the REB for collection by the researcher. Custodians should have an established review process for research requests that should, among other activities, ensure that the information being requested matches the information approved by the REB.

- When a custodian discloses information to a researcher, it does not transfer "ownership" of the data and the custodian should clearly establish expectations regarding retention, destruction and future use of data. Future use includes new datasets created using data, in whole or in part, disclosed by the custodian.

- If the custodian provides access to personal health information beyond what has been explicitly approved by the REB, the disclosure is contrary to *PHIA* and the custodian is accountable for that disclosure. Similarly, it is not sufficient for *PHIA* compliance purposes to assert that a research proposal **implies** access to certain personal health information. The personal health information intended to be accessed must be clearly and explicitly indicated in the REB approval documents. Further, if the research involves both direct and indirect collection, it must indicate what information will be directly collected from participants and what information will be indirectly collected from other sources.

- REB approval is based on the statutory requirements of *HREAA* that focus on ethics. Custodians cannot rely on REB approval to satisfy their *PHIA* obligations to protect the privacy of personal health information. When considering a request from a researcher for access to personal health information after REB approval, the decision whether to disclose the information is a discretionary decision by the custodian. Under *PHIA*, the REB is not accountable for the disclosure – the custodian is accountable for the disclosure. The onus is therefore on the custodian to come to its own conclusion, after considering all relevant factors, including: whether the safeguards proposed by the researcher are appropriate; how the data is to be accessed; whether it is necessary to allow the researcher to access the data directly or whether it can be provided to the researcher by staff of the custodian; whether the researcher's arrangements for retention and destruction are sufficient, etc.

Before the custodian grants access to a record of personal health information on the basis that a research subject has provided consent for the researcher to access it, there is an onus on the custodian to review the consent to ensure that it meets the requirements of *PHIA*, including that the consent form be explicitly clear as to what information is intended to be accessed by the researcher. Asserting that knowledgeable consent is in place to access personal health information on the basis that it is implied in the consent form that such access would be necessary to accomplish the purpose of the research is not acceptable.