CAREB-ACCER vREB Case Study Debrief # 4: Canadian Registry of Neonatal Patients (Case has been adapted from Canadian Neonatal Network Database research proposal, courtesy of the Principal Investigator and Island Health)

The Virtual REB (vREB) is a CAREB-ACCER professional development initiative that facilitates discussion on a series of research ethics case studies. While the cases presented are study overviews rather than full protocols, they are designed to include enough information to stimulate thoughtful discussion of the ethical issues entailed.

Case Studies are posted for CAREB-ACCER members across Canada to contribute their thoughts on relevant ethical issues as if conducting a research ethics review. Results will be compiled and presented in a case debrief that will be archived on the CAREB-ACCER website as a training resource which can be used by CAREB-ACCER members to support the orientation and training of REB members and professionals within their own institutions.

We acknowledge that research ethics opinions are often seen through the lens of context and are open to interpretation. As such, opinions may vary; however, these variations may be the seeds of professional discussion, learning, and development which are the goals of this exercise. If you have comments on the case or debrief, we encourage you to start or join a discussion on the vREB section of the CAREB-ACCER online forum

CAREB-ACCER received a total of 4 responses to the case study survey with only 1 complete response.

Case #4 Case Study Summary

Methodology of Case #4:

This is an on-going database involving data collection from patient charts only. Concurrently, with 30 other NICU's in Canada, all live-born infants born/admitted to NICU at >22 weeks gestation or >400g will be enrolled. A research assistant will abstract data from patient charts into a computer program. At regular intervals, this data will be electronically transferred using secured means to a central database at the Canadian Neonatal Network Coordinating Centre. Patient identifiers will be stripped prior to transfer, and a code substituted for each patient. In the event that a child is transferred to another hospital, the unique identifier will be made available to the receiving hospital. Patients will not be contacted during the study, and no consents will be obtained. Only the research

assistant collecting the data and the site investigator will have access to the data. Strict confidentiality will be observed. Individual data at each site will be available to site investigators at each site for their own research. Aggregate data at the CNN Coordinating Centre will be available to investigators from other NICUs across Canada, but study sites and patient identity will remain anonymous at all time points.

Issues identified by the VREB Advisory

1. Requirement of REB review.

Some VREB advisors considered that the study may constitute a Quality Assurance/ Quality Improvement (QA/QI) project, which is exempted from REB review.

Per the article 2.5 of the TCPS2,
Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this Policy, and do not fall within the scope of REB review.

It is critical to determine if the study is deemed QA/AI based on the Guidance/requirements of hosting institutions and the provincial legislations. The criteria of QA/QI may vary among institutions and provinces. Some advisors recommended using QA/QI identification tool, i.e. ARRECI, to determine if the study is deemed QA/AI.

2. Due to the big scale and nation-wide data collection, the development of a governance framework should be considered and involve local Principal Investigator (PI), privacy, REB, clinicians, data steward, and Information Management/Information Technology (IM/IT) specialists.

3. Misuse of the terminology of the categorizations of the collected information.

The terminology of “coded” and “anonymous” were used in the Methodology.

Per the Chapter 5, section A of the TCPS2, the types of information are categorized as follows:

- *Directly identifying information – the information identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number).*
- *Indirectly identifying information – the information can reasonably be expected to identify an individual through a combination of indirect*

identifiers (e.g., date of birth, place of residence or unique personal characteristic).

- *Coded information – direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the principal investigator retains a list that links the participants' code names with their actual name so data can be re-linked if necessary).*
- *Anonymized information – the information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.*
- *Anonymous information – the information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low.*

4. The lack of details of the categorization/types of data collection.

There is no detailed information regarding which types of information/clinical outcome will be collected. A data collection sheet identifying all intent-to collect variables is deemed essential for REB review.

5. The lack of nation-wide scope in the privacy legislations.

The project recruits data from across Canada. The researchers would need to look at and understand all provincial privacy requirements and coordinate to set up protocol on a national level.

6. The lack of justification on the waiver of consent.

Per the article 3.7 of the TCPS2,
The REB may approve research without requiring that the researcher obtain the participant's consent in accordance with Articles 3.1 to 3.5 where the REB is satisfied, and documents, that all of the following apply:

(a) the research involves no more than minimal risk to the participants;
(b) the lack of the participant's consent is unlikely to adversely affect the welfare of the participant;
(c) it is impossible or impracticable to carry out the research and to answer the research question properly, given the research design, if the prior consent of the participant is required;
(d) whenever possible and appropriate, after participation, or at a later time during the study, participants will be debriefed and provided with additional pertinent information in accordance with Articles 3.2 and 3.4, at which point they will have the opportunity to refuse consent in accordance with Article 3.1; and
(e) the research does not involve a therapeutic intervention, or other clinical or diagnostic interventions.

7. The collection of the identifiable information without obtaining consent may limit the future use of the proposed registry.

There is a great feasibility for the proposed registry to be used in the research field other than currently purposed, especially involving the identifiable information without obtaining consent.

Per the Chapter 5, section D of the TCPS2, “Secondary use refers to the use in research of information originally collected for a purpose other than the current research purpose”

Per the article 5.5,
Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for these purposes if the REB is satisfied that:

(a) identifiable information is essential to the research;
(b) the use of identifiable information without the participants’ consent is unlikely to adversely affect the welfare of individuals to whom the information relates;
(c) the researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information;
(d) the researchers will comply with any known preferences previously expressed by individuals about any use of their information;
(e) it is impossible or impracticable to seek consent from individuals to whom the information relates; and
(f) the researchers have obtained any other necessary permission for secondary use of information for research purposes.

If a researcher satisfies all the conditions in Article 5.5(a) to (f), the REB may approve the research without requiring consent from the individuals to whom the information relates.

Therefore the advisory board felt that the case study did not make an argument for:

- If the lack of consent is likely to affect participant welfare;
- If there is adequate protection of privacy of individuals;
- If researchers will comply with patient’s stated preferences in their health care record;
- If consent of participants is impracticable;
- The protocol would need to meet provincial privacy guidelines to use patient health chart information for the purposes of research (PHIPA, FIPPA, etc.)

8. The lack of any descriptions of the governance structure.

Because the data is identifiable patient chart information (that will be transferred/shared with another hospital) the safeguarding of information requires more detail; the REB would need to make sure that the extracting of data, data storage, transmission of data, data retention, and data destruction meets provincial and federal privacy standards (PHIPA, FIPPA, etc.).

The VREB Advisory determined that a governance body is deemed essential and recommend the PIs develop a framework of the governance to oversee the general operations of the proposed registry.