The Function of Academic Research Ethics Boards in Governing Privacy, Confidentiality, and Security Issues in Studies Using Personal Health Information

Background: Research ethics boards (REBs) play a critical role in the protection of the rights and interests of human subjects in biomedical and behavioural research. Recent U.S. reports have raised concerns that REBs are not giving sufficient attention to individuals' privacy and confidentiality. These concerns could equally be levelled at Canadian REBs. Existing and upcoming privacy laws at the federal and provincial levels vary substantially in their requirements. However, they generally leave considerable scope for access to clinical and administrative records for academic research. Research institutions must demonstrate good stewardship of the information disclosed to them if they are to retain a privileged access to this information. An important component of that stewardship is the function of REBs in ensuring fair information management practices in academic research. However, uniform criteria for assessment of observational studies for their impact on privacy and confidentiality are lacking, leaving REBs to their own means. Nor is there systematically collected information on the variation in how REBs in Canada handle privacy and confidentiality issues in the research protocols they review.

Goal and Objectives: The long-range goal of this research is to improve the consistency in how REBs handle issues of privacy and confidentiality intwo types of studies: (1) those involving the secondary use of personal information for health research, and (2) those involving the development of prospective registries and biobanks. The objectives of this study are: (1) to document the ways in which REBs vary in their handling of privacy, confidentiality, and information security issues when reviewing research protocols involving administrative or clinical records, registries, biobanks, or secondary use of biological samples, (2) to identify "best practices" and common challenges in the field, (3) to ascertain the concerns of REB chairs around oversight of the protection of personal information and the ability of REBs to address them effectively, and (4) to develop a data collection instrument that will provide a common set of questions that REBs can use to ask with regard to privacy, confidentiality, and data security.

Methods: The study will proceed in 2 phases. In Phase 1, using semi-structured interviews, the co-investigators will personally interview (a) chairs and coordinators of 6 REBs that review a high volume of database studies and (b) researchers from the corresponding research institutes, to determine best practice. Based on the information provided from the semi-structured interviews, we will develop data collection tool, for use in Phase 2, which captures the variation in practice.

In Phase 2, all REBs affiliated with Canadian Faculties of Medicine will be invited to participate. Data will be gathered through a combination of:

(1) interviews with REB Chairs and administrative coordinators, and with a sample of researchers, and

(2) review of a sample of protocols and related minutes of meetings and correspondence between the REB and the principal investigator.

Interviews and case study review will be conducted in similar fashion as in Phase 1, with the exception that there will be a higher degree of structure to the questions – using both fixed and open-ended responses – to ensure greater consistency in responses across sites.

Phase 2 will result in three tangible products:

(1) A report describing the variation across REBs with regard to: (a) presence of policies and procedures addressing privacy and confidentiality issues in these types of research; (b) consistency of institutional policies and practices with published principles on fair information

practices; (c) monitoring of compliance with REB requirements; and (d) how decisions and deliberations are documented in REB minutes. Recognizing that there will be a gap between the practices being recommended by those advocating greater protections for personal health information and current practice, the report will suggest methods to better equip REBs to handle these issues, and the resource implications for REBs.

(2) Case studies for use in developing an educational program for REBs. Permission will be requested of the REBs and investigators whose protocols will be used to develop de-identified standardized case studies based on the protocols identified during site visits.

(3) A finalized data collection tool for REBs that can be used as a template in the review of future protocols involving secondary use of personal information or biological samples, or involving the development of registries or biobanks.

Policy Relevance:

The regulatory environment for REBs is in flux.

(1) Data protection requirements vary from one jurisdiction to the next. While it has been recognized for some time that a harmonized approach to these issues is essential for cross-jurisdictional research and the roll-out of infohighway plans, this has not yet been realized and regulators are coming to recognize that there is no “easy fix”. The issue of conformance with new privacy legislation is a priority issue with the Ethics Division of the CIHR.

(2) In Canada, plans are underway to formally regulate (through legislation) research involving human subjects. This will include accreditation of REBs. Management of privacy and confidentiality will certainly be a prominent issue.

This project will address both these legislative issues with regard to privacy, confidentiality, and related issues. One product of the research will be the development of a common comprehensive framework for reviewing privacy, confidentiality, and data security issues when reviewing research protocols involving secondary use of personally identifiable information.

In contrast to the “top-down” approach that usually occurs when legislation and regulations are developed, the framework will be developed from the “bottom-up”, providing researchers the opportunity to inform both the process of harmonizing data protection legislation across Canada and the development of accreditation standards for REBs around these issues. This project sets the tone for such activities – through a continuous quality improvement process.