



## Research Ethics Board Guidance for Investigators

### Personal Health Information Protection Act, 2004 & REB Review of Health Record/Database Research

#### Context

In November 2004 the Ontario *Personal Health Information Protection Act, 2004 (PHIPA)* came into effect regulating the role of health information custodians and the collection, use and disclosure of personal health information. It also describes the role of the REB in its review of health information for research purposes.

PHIPA assigns to REBs the responsibility for determining when consent can be waived. Waiver of consent will only be considered for research involving existing personal health information commonly referred to as health record or database research. As a result, and following review of this legislation and the CIHR draft best practices guidelines “Guidelines for Protecting Privacy and Confidentiality in the Design, Conduct and Evaluation of Health Research”, the Sick Kids REB criteria are found listed below for those investigators who wish to request a waiver of consent.

#### REB Review Procedures

- A waiver of consent will only be considered for research involving existing personal health information eg., health chart research, for which there will be no patient contact. *If it is found that the health record is incomplete and patient or family physician contact is necessary to complete the record, subject consent will be required.*
- Presentation of information for publication must always be in a non-identifiable format to ensure the anonymity of subjects. Special caution should be exercised when presenting information in table format.
- As part of their application submission, investigators must now sign a data privacy agreement (found in the application form revised Feb 05) which sets out the restrictions placed on the investigator for research use of the personal health information.
- Based on the criteria listed below (and also found in the application form) investigators must provide a rationale for requesting a waiver of consent.
- The rationale will be reviewed by the REB Chair and, if consent waiver is granted, application review and approval will proceed. The Chair’s supported rationale will be noted with the approval.
- If, on the other hand, the Chair does not support the waiver of consent, a consent form will be sought by REB office staff before the application is reviewed.
- The REB consent form template has been modified for this purpose and is now posted on the REB website.

## **Waiver of Consent**

The following conditions must be met before a waiver of consent will be considered by the REB;

- the objectives of the research cannot be reasonably accomplished without using personal health information
- there are adequate safeguards to protect the privacy of individuals
- there is a public interest in this research while protecting the privacy of individuals

## **Criteria for an investigator to consider when requesting a waiver of consent**

1. the sample size is so large that obtaining consents are impracticable
2. the subjects have graduated to adult services or are otherwise too difficult to locate making obtaining consents impracticable
3. the subject group under investigation has a high mortality rate so can not be contacted without causing distress to the family eg., children with severe heart malformations
4. because of the unique subject group characteristics, there is a greater risk of sample bias which would invalidate the research eg., research concerns family disintegration issues
5. the request for chart review is only to determine study feasibility or the appropriate sample size and not to conduct research
6. Other

## **Data Privacy Agreement**

PHIPA also requires that researchers enter into a data privacy agreement with the Health Information Custodian (HIC) eg., health records department, custodian of a clinical database. This agreement sets out the conditions for research access and use of personal health information for research purposes. It is also included in the short application form revised Feb 05.

Investigators who wish to access personal health information under the control of external HICs will be asked to sign their data privacy agreement. As with all agreements, investigators must submit these agreements to the Sick Kids Contracts Office for review and approval before signing.

## Definitions

### **Personal health information (PHI)**

*(ref s.4 p12)*

PHI includes identifying information about an individual in oral or recorded form that;

- relates to his or her physical or mental health
- relates to providing health care, including identifying a provider of health care
- is a plan of services within the meaning of the Long-Term Care Act
- relates to the donation of a body part or bodily substance
- relates to payments or eligibility for health care in respect of the individual
- is a health number
- identifies a substitute decision-maker of that individual
- is in a record where the record contains any of the above information

### **Health Information Custodian (HIC)**

A HIC is a listed individual or organization under *PHIPA* that, as a result of their power or duties, has custody or control of personal health information. These include health care practitioners, and hospitals.

### **Agent**

An “agent” of a health information custodian (HIC) includes anyone who is authorized by the HIC to do anything on behalf of the HIC with respect to personal health information.

### **Data Privacy Agreement**

An agreement between a HIC and an investigator which details the restrictions under which the researcher may use and disclose the information.