Holland Bloorview
Kids Rehabilitation Hospital

PRIVACY IN RESEARCH GUIDANCE DOCUMENT

Holland Bloorview is committed to protecting the privacy, confidentiality and security of personal health information (PHI) in their possession and has policies in place with respect to the collection, use, disclosure and retention of PHI (Holland Bloorview Policy.This policy commitment is governed in part by the Privacy Legislation in Ontario, Personal Health Information Protection Act (PHIPA), the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2), and relevant federal regulations including Health Canada Therapeutic Products Directorate Food and Drug Regulations, Clinical Trials, Division 5.

Personal Health Information

PHI is defined by PHIPA as follows (PHIPA section 44.1):

- identifying information about an individual in oral or recorded form, if the information,
  - relates to the physical or mental health of the individual, including information that consists of the health history of the individual's family,
  - relates to the providing of health care to the individual, including the identification of a person as a provider of health care to the individual,
  - is a plan of service within the meaning of the *Home Care and Community Services Act, 1994* for the individual,
  - relates to payments or eligibility for health care, or eligibility for coverage for health care, in respect of the individual,
  - relates to the donation by the individual of any body part or bodily substance of the individual or is derived from the testing or examination of any such body part or bodily substance,
  - is the individual's health number, or
  - identifies an individual's substitute decision-maker.

What Is Identifiable Information?

According to the TCPS2 (Chapter 5), information is identifiable if it may reasonably be expected to identify a person, when used alone or combined with other available information. Information is nonidentifiable if it does not identify a person, for all practical purposes, when used alone or combined with other available information.

The following categories provide guidance for assessing the extent to which information could be used to identify a person:

Directly identifying information
The information identifies a specific person through direct identifiers (e.g., name, health card number, hospital MRN, social insurance number…).
Although with appropriate consent and REB approval directly identifying information can be collected from research participants for research purposes, there needs to be strong justification for wanting to collect and store directly identifying information about the participants.

Indirectly identifying information
The information can reasonably be expected to identify a person through a combination of indirect identifiers (e.g., date of birth, full address, full postal code or unique personal characteristics including a person's voice, rare disease diagnosis, unique body markings or features that are either inborn, the result of the disease, or artificially added such as tattoos…).

Coded (de-identified) information
Direct identifiers are removed from the information and replaced with a unique code. Depending on access to the master code breaking file, or inclusion of strong indirect identifiers, 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 any information that can directly or indirectly link research information to the participant. The study participant are never provided with a unique code. The risk of re-identification of persons 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 persons is low or very low. Ethical concerns regarding privacy decrease as it becomes more difficult (or impossible) to associate information with a particular person. These concerns also vary with the sensitivity of the information and the extent to which access, use or disclosure may harm a person or group.

<u>Personal Health Information in Research</u>
All research involving human participants and all other research activities which even in part, involve such research, regardless of sponsorship undertaken at Holland Bloorview or under its auspice must be reviewed and approved by the Holland Bloorview Research Ethics Board (REB) or other Boards of Records and comply with PHIPA.

The REB's review and approval process ensures that the research plan makes adequate provision to protect the privacy of research participants and to maintain the confidentiality of the research data. The REB and Privacy Office can provide guidance on appropriate methods to safeguard PHI throughout the

complete research cycle from its collection, use, dissemination, retention and disposal (TCPS2 Article 5.3).

PHIPA sets out specific requirements for all parties involved in the disclosure of PHI for research purposes (PHIPA section 44.1, 44.2, 44.3, 44.6):

The Researcher must:

- submit a research plan to the REB and obtain REB approval. The research plan should include the following:
    - the objectives of the research cannot reasonably be accomplished without using the personal health information that is to be disclosed;
    - at the time the research is conducted, adequate safeguards will be in place to protect the privacy of the individuals whose personal health information is being disclosed and to preserve the confidentiality of the information;
    - the public interest in conducting the research and the public interest in protecting the privacy of the individuals whose personal health information is being disclosed;
    - there is an appropriate participant consent process for the information being disclosed
- Ensure they follow the REB approved plan.

Use of Linking Logs

The use of a unique study identifier or code to identify a participant is considered best practice. Unique study identifier/study code must not include any Personal Health Information (PHI) of research participants, such as name, initials, full/partial date of birth (DOB), and full/partial medical record number (MRN).

Initials of First name Last name on Data Collection Forms/Case Report Forms (CRFs)

Initials are considered as an identifier under PHIPA and does not add scientific value to research. Initials are also not a unique identifier, hence collecting initials on data collection forms/CRFs is not permitted.

Date of birth on Data Collection Forms/CRFs

If the study sponsor provides data collection forms or CRFs that include identifying data fields (e.g., full DOB without justification), research teams should use 'dummy dates' in order to complete the required fields. For example, if study CRFs require full DOB, study teams can use the '1st' or '15th' of the month for all participants. This ensures that exact DOB is not sent off site. If a study team is requesting full DOB collection, the team must provide a scientific justification to the REB why this data must be collected, and how it will be safeguarded.

Data Collection

Research data must be collected on institutionally approved platforms (e.g. Google cloud health care, HB REDCap). Should a research team need to collect data on any other electronic platforms, institutional approval (e.g. Privacy Office, Information Management Technology (IMT), BRI…) will need to be obtained prior to submitting to the REB.

Research involving video recording

If the research activities involve the video recording of the participants, the following must be explained:

1. Is video recording a mandatory part of the research? If yes, why is it mandatory?
2. Will identifiable features (face, tattoos, birth marks, etc.) be blurred, i.e. will a form of deidentification take place prior to the video becoming part of the research data?
    a. How will it be de-identified
3. Who will have access to the video recording and for what purpose?
4. Where will the video recordings be stored, and when will it be destroyed?
5. How can participants request withdrawal of their video recording?

When Using Email

Email is considered a non-secure form of communication as it may be accessed by unauthorized third parties. As a result, consent should be obtained prior to sending out any information in an email. When consenting to contact (either through the phone recruitment or study consent process), the potential participant should be informed that email communications are not secure, and that personal information may be included in the email. This consent should be documented in the study files. When using email, the following guidelines need to be followed:

1. The sender's Holland Bloorview email account should be used (research teams cannot use their personal email);
2. Do not use mass emails;
3. Avoid sending emails with sensitive personal health information;
4. Forms containing personal health information (e.g., consent forms that describe specific disease conditions) must not be sent without prior consent

The Holland Bloorview REB requires the following information and documents be submitted with the application:

1. Information about the source of the email list and whether consent has been provided to be contacted by email;
2. A copy of the proposed email text, subject line and any graphic used in the email;
3. A copy of any follow-up emails and frequency with which these are to be sent. A maximum of 3 follow-up emails are permitted; after this, if no contact has been established, then a potential participant is deemed as having refused to be part of the study/lost to follow-up.

Data Storage

Once REB approval is granted, agreements are finalized and the researcher has been provided the PHI/PII, from the information custodian (i.e. Holland Bloorview or an external institution) , the researcher must:

- comply with the conditions, if any, specified by the REB in respect of the research plan;
- use the information only for the purposes set out in the research plan as approved by the REB;
- not publish the information in a form that could reasonably enable a person to ascertain the identity of the individual;
- not disclose the information except as required by law and subject to the exceptions and additional requirements, if any, that are prescribed;
- not make contact or attempt to make contact with the individual, directly or indirectly, unless the custodian first obtains the individual's consent to being contacted;
- notify the custodian immediately in writing if the researcher becomes aware of any breach

Breaches of privacy in research can occur if:

- PHI was collected, used, or disclosed without prior REB approval and finalized agreement(s)
- The privacy safeguards described in the REB approved research plan failed to maintain privacy and confidentiality and there has been unauthorized collection, use, disclosure or disposal of PHI

In the event that a breach of privacy in research occurs, the breach must be reported by the Local Principal Investigator to the information custodian, the REB, and Holland Bloorview Privacy Officer and will be dealt with in accordance with established hospital practices.

Required steps to protect privacy in research:

- Ensure that all research team members have received adequate privacy and confidentiality training
- Store all research data under a two-lock system (eg. restricted access folder in an institutionally approved network drive)
- All research data must be collected on hospital or institutionally approved networks, data collection platforms or portable electronic devices.
- Ensure that electronic research data are stored on a controlled access folder on the hospital or institution network rather than a computer hard drive or portable device
- De-identify data and maintain the coding key separate and secure from the research data
- Ensure that data sharing agreements are in place if research data will be removed from the hospital/institution premises
- Ensure a review process is in place prior to sending data externally to ensure it is de-identified

- Limit the amount of PHI you collect to ensure you are not using the data for purposes other than those for which they were collected (as described in REB approved research plan)
- Limit the number of people on the research team who will have access to the research data and only provide access based on the team member's role in the research study.

Data Transfer

If data or materials are being transferred to or from Holland Bloorview, details on how they will be adequately protected and safeguarded during the transfer with external sites/service providers should be described to the REB. No identifying information should ever leave Holland Bloorview. If you are exchanging data or materials with another site/service providers, you will require a data or materials transfer/sharing agreement. Please consult with the Grants, Contracts and Awards team regarding the requirements for a transfer/sharing agreement. The REB will ask for evidence that the Grant, Contracts and Awards team was contacted for this purpose.

Additionally, institutional approval (e.g. Privacy office, IMT, BRI…) will be required when data is to be collected/transferred/shared on a non-institutionally approved database.

Data Destruction

Data must be stored by researchers for a minimum of 7 years post study closure or 15 years from end of study in the case of Health Canada regulated studies. Details of how data will be destroyed should comply with both the destruction plan submitted and approved by the REB as well as hospital and Institutionally approved processes (as per the Document Management Policy).

For more information contact:

The Holland Bloorview Research Ethics Board
Tel: (416) 425-6220 ext.3161
researchethicsboard@hollandbloorview.ca

The Holland Bloorview Privacy Officer
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privacy@hollandbloorview.ca

References:
PHIPA: http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm
TCPS2: https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html
Health Canada Food and Drugs Act Division 5 Drugs for Clinical Trials Involving Human Subjects:
http://hc-sc.gc.ca/dhp-mps/compli-conform/clini-pract-prat/reg/1024-eng.php