

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 #IM 020, 033, 034 and 062). 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.

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.

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) and comply with PHIPA.

The REB 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 REB must review the research plan and determine whether:

- the objectives of the research can 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;
- obtaining the consent of the individuals whose personal health information is being disclosed would be impractical. The specific requirements that must be met for the Holland Bloorview REB to waive or alter informed consent are described in policy REB-703 .

The Information custodian may disclose PHI about a research participant only when the researcher submits to the custodian:

- a request in writing,
- a research plan that describes the affiliation of each person involved in the research and describes the nature and objectives of the research and the public or scientific benefit of the research that the researcher anticipates
- a copy of REB Ethical Approval Notice

Once REB approval is granted and the information custodian has disclosed PHI to the researcher, 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
- 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.

Recommendations 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. password protected computer in a locked office)
- Encrypt all research data that will be temporarily stored and transferred using portable devices, and transfer these data to the hospital network immediately (NB: Portable electronic devices even when encrypted must not be used for anything other than short term storage/transfer and wiped once the data are transferred to the network.)
- Ensure that electronic research data are stored on a controlled access folder on the hospital network rather than a computer hard drive or portable device
- Anonymize identifiable data by destroying the coding key or de-identify data and maintain the coding key separate from the research data
- Ensure that data sharing agreements are in place if research data will be removed from the hospital premises
- 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.

For more information contact:

The Holland Bloorview Research Ethics Board

Tel: (416) 425-6220 ext. 3507

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The Holland Bloorview Privacy Officer

Tel: 416-425-6220 ext. 3467

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References:

PHIPA: http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm

TCPS2: http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf

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>