Holland Bloorview
Kids Rehabilitation Hospital

	REB REVIEW OF RESEARCH		
POLICY: REB-703	**WAIVER OR ALTERATION OF INFORMED CONSENT**		
This policy pertains to:	The activities of the Research Ethics Board (REB) operating under the authority of Holland Bloorview Kids Rehabilitation Hospital		
Responsibility for executing this policy:	Chair, Holland Bloorview REB (or designate)		
Effective date:	September 30, 2014	**Supersedes documents dated:**	V1: August 2013
Approved:	Chair of the REB Research, Teaching & Learning Advisory Committee		

1. PURPOSE:

The purpose of this SOP is to describe the general requirements that must be met in order for a waiver or alteration of informed consent to be approved by the REB.

2. POLICY STATEMENT:

The REB may waive or alter some or all of the elements of the informed consent form (ICF) or process as described in REB-701 and REB-702 in minimal risk research.

A waiver of consent implies that no consent process is required. In other words, given a waiver of consent, there is no information and consent form or verbal review of study information with participants.

An alteration of consent implies a departure from the elements or the ICF or the consent process as described in SOPs REB-701 and REB-702.

It is the responsibility of the researchers to justify the need for either a waiver or alteration of informed consent.

REFERENCES

TCPS2 Article 3.7

CAN/CGSB-191.1-2013 – (4.4.4.2.12)

3. SPECIFIC POLICIES

3.1 Waiver or alteration of informed consent

TCPS2Article 3.7

45 CFR 46.116

The REB may approve research without requiring that the researcher obtain the participants' consent where it is satisfied, and documents, that all of the following apply:

- **a.** the research involves no more than minimal risk to 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; and,
- **e.** the research does not involve a therapeutic intervention or other clinical or diagnostic interventions

The REB may also consider:

- **a.** the manner in which the research data/information will be kept confidential;
- **b.** whether the public interest in conducting the research outweighs the public interest in protecting the privacy of the individuals; and,
- **c.** the vulnerability of participants, particularly children who do not have the capacity to consent.

3.2 Research Involving Partial Disclosure or Deception

There are some scientific disciplines in which the research objectives can be carried out only if the participants do not know the true purpose of the research in advance.

TCPS2 Article 3.7

In cases where the researcher wishes to withhold or partially disclose pertinent information or deceive participants, the REB may approve research that meets the requirements of a waiver or alteration of consent as described in Section 3.1 above.

Additionally, the researcher must:

TCPS2 Article 3.7

a. describe the nature of the information to be withheld;
b. describe the plan for debriefing participants including:
   - an explanation of why participants received less than full disclosure and the necessity for deception
   - details about the importance of the research
   - an expression of concern for the welfare of participants
   - details regarding the timing for debriefing participants.

c. prepare a script that the researcher will follow for debriefing participants.
d. obtain consent from the participant or their authorized third party prior to using the data that was obtained through partial disclosure or deception.
e. offer to remove the participant's research data if they or their authorized third party refuses to provide consent. If the research design does not allow for removal of data, the researcher must ensure that the identity of the participant is protected at all times during and following completion of the project.
f. refer participants to the REB Office if they express concern about the conduct of the project at the time of debriefing or contest the limits imposed on withdrawing their data.
g. report to the REB any concerns expressed by participants related to the conduct of the project at the time of debriefing.

3.3 FDA Regulated Research

The REB may not waive informed consent except under specific provisions for emergency research per 21 CFR 50.24. 21 CFR 50.24

Revision History

V2/July 2014: CAN/CGSB-191.1-2013 references incorporated to reflect compliance. Changed Research Advisory Committee to Research, Teaching & Learning Advisory Committee.