WOMEN'S COLLEGE RESEARCH INSTITUTE
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Research Ethics Board Standard Operating Policies and Procedures

Waiver or Alteration of Informed Consent

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ISSUED BY:	Research Ethics Office		
APPROVED BY	Vice President, Research		

The WCH REO webpage version of this document is considered the most current.

Please ensure that you have reviewed all linked documents and other reference material within this SOP

1.0 POLICY STATEMENT:

The purpose of this Standard Operating Procedure (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 Women's College Hospital (WCH) Research Ethics Board (REB).

The WCH REB may waive or alter some or all of the elements of the informed consent form (ICF) or process as described in *WCH REB Informed Consent Elements SOP* and *WCH REB Informed Consent Process SOP* in research that is assessed to be minimal risk.

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 *WCH REB Informed Consent Elements SOP* and *WCH REB Informed Consent Process SOP*.

2.0 DEFINITION(S):

See Glossary of Terms

3.0 RESPONSIBILITY:

This SOP applies to the REB Chair, Vice-Chair, REB Members, Research Ethics Office (REO) staff and Investigators.

The Investigator is responsible for justifying the need for either a waiver or alteration of informed consent

The REB is responsible for detereming whether informed consent exemptions or waivers are appropriate.

4.0 PROCEDURES:

4.1. Waiver or Alteration of Informed Consent

The REB may approve research without requiring that the Investigator obtain the participants' consent where it is satisfied (and clearly documents), that all of the following apply to the research project (see Article 3.7A of the TCPS 2):

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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 intervention.

In accessing the appropriateness of a waiver of consent, 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 who do not have the capacity to consent.

4.2. 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.

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 an alteration of consent as described in 4.1 above.

Additionally, the researcher must:

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 full debriefing of participants including re-confirmation of informed consent.

c. Prepare a script that the researcher will follow for debriefing participants or a debriefing document that is reviewed with the participant.

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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.

4.3. FDA Regulated Research

The REB may not waive informed consent except under specific provision for emergency research per *Code of Federal Regulations* Title 21 part 50.24.

5.0 REFERENCES:

1. Holland Bloorview Research Ethics Board Standard Operating Procedure (REB-703), Waiver or Alteration of Informed Consent

2. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2), Articles 3.7,

3. US Food and Drug Administration (FDA) Code of Federal Regulation: 21 CRF 50.24, 45 CFR 46.116

4. Women's College Hospital Research Ethics Board Standard Operating Procedure (REB-SOP-VII-01.001, REB-SOP-VII-02-001)