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

Initial Review of Research and Criteria for REB Approval

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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 requirements of research proposals involving human participants for approval by the Women's College Hospital (WCH) Research Ethics Board (REB).

All research involving human participants must meet certain criteria before WCH REB approval may be granted. The approval criteria are based on guiding ethical principles of the most current version of the Tri-Council Policy Statement (TCPS) and other applicable regulations and guidelines.

Initial WCH REB approval of research is based on assessment of a complete application package. The WCH REB may consult the investigator for additional information as necessary.

In addition to WCH REB approval, the requirements of the Women's College Research Institute (WCRI) must also be met before the research can begin.

Following initial review of the protocol, the WCH REB should be prepared to make a determination as to the approvability of the research.

2.0 DEFINITION(S):

See Glossary of Terms

3.0 RESPONSIBILITY:

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

The REB members are responsible for determining whether or not a research study meets the criteria for approval based on ethical principles.

The REB Chair or designee is responsible for ensuring the REB members have adequate training, expertise and guidance to conduct their reviews and to make decisions regarding the ethical acceptability of research.

4.0 PROCEDURES:

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4.1 Minimal Criteria for Approval of Research

In order for a research study to receive WCH REB approval, the WCH REB must find that:

4.1.1 There is a state of clinical equipoise where interventions are being compared;

4.1.2 The research will generate knowledge that could be generalized and lead to improvements in health or well-being;

4.1.3 The methodology is scientifically sound and capable of answering the research question;

4.1.4 Risks to research participants are minimized by:

- using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk, and
- using procedures already being performed on the participants for diagnostic or treatment purposes, whenever appropriate;

4.1.5 Risks to research participants are reasonable in relation to the anticipated benefits, if any, and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, the WCH REB shall consider those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that the participants would receive even if not participating in the research). The WCH REB should not consider long-range effects of applying the knowledge gained in the research;

4.1.6 Selection of research participants is equitable. In making this assessment, the WCH REB will take into account the purposes of the research and the research setting. The WCH REB considers the scientific and ethical reasons for including any vulnerable populations, if applicable;

4.1.7 Sound scientific and ethical reasons for excluding classes of persons who might benefit from research are articulated in the protocol:

- Non-English speaking participants should not be systematically excluded because of inconvenience in translating informed consent documents;
- Participants should not be taken from one group simply because it is convenient;
- The research should include all genders when appropriate, and does not arbitrarily exclude the participation of persons of reproductive ages, the elderly, youth or persons with disabilities;

4.1.8 When some or all of the research participants are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study and in the REB review process to protect the rights and welfare of these participants;

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4.1.9 The amount and method of payment to participants will not likely lead to coercion or undue influence and that information regarding payment to participants, including methods, amounts and schedule is provided to participants as applicable;

4.1.10 Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with and to the extent required by applicable regulations and guidelines. In certain situations, the REB may approve a consent procedure that does not include, or which alters (e.g. deferral), some or all elements of informed consent, or waive the requirement to obtain informed consent;

4.1.11 The informed consent form accurately explains the research and contains the required elements;

4.1.12 The informed consent process is clearly described in the application (Toronto Academic Health Science Network (TAHSN) form and protocol);

4.1.13 There are provisions for on-going data and safety monitoring, as evidenced by a data safety monitoring plan (DSMP), that are appropriate to the size, complexity, phase, and level of risk of the study. The WCH REB may recommend the use of a Data Safety Monitoring Board (DSMB) to enhance participant protection;

4.1.14 Where appropriate, there are adequate provisions to protect the privacy of the participants and to maintain the confidentiality of data;

4.1.15 There are adequate provisions for continued access to the agent or device, or adequate replacement, after the study is completed when appropriate;

4.1.16 There are adequate provisions for timely publication and dissemination of the research results;

4.1.17 The research has been submitted to Health Canada if applicable, and the Health Canada No Objection Letter (NOL) has been issued.

4.2 Additional Criteria

4.2.1 Studies proposing access to or collecting of personal health information (PHI) require consideration of additional items to protect the privacy of PHI. Therefore, the WCH REB must find that:

- Authorization is obtained from participants or their legally authorized representative for the collection, use or disclosure of their PHI, or the WCH REB has approved a waiver of such authorization;

- The PHI will be contained in a de-identified limited data set with appropriate safeguards to maintain privacy (see guideline on Unique Study Identifiers, Key Files and Access Logs).

4.3 Minimum Criteria for Approval to Conduct the Research

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In order to receive approval to participate in research, the WCH REB must be satisfied that:

4.3.1 The application (TAHSN form) has been signed by the principal investigator (PI) and his/her department/division/ program head;

4.3.2 The investigator has the qualifications to conduct the research as attested to by the department/division/program head;

4.3.3 Any potential conflicts of interest (COIs) are managed appropriately to prevent any compromises to the safety or well-being of participants or the integrity of the data;

4.3.4 The recruitment methods respect the privacy of individual participants;

4.3.5 The informed consent form(s) accurately explain the research and contain the required elements;

4.3.6 The informed consent process is clearly described in the application;

4.3.7 There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data;

4.3.8 There are no restrictions on timely publication and dissemination of the research results;

4.3.9 Clinical trials are registered with a recognized and easily web-accessible public registry (e.g. clinicaltrials.gov) and the registration number has been provided to the WCH REB.

4.4 Length of Approval Period

4.4.1 The REB shall review research studies appropriate to the degree of risk, but not less than once a year;

4.4.2 The REB may require review more often than annually when there is a high degree of potential risk to participants relative to the population;

4.4.3 The REB may consider review of research more often than annually when any of the following are true:

- Proposed procedures have not been used in humans,
- The stage of the research is such that many of the risks are unknown,
- More than minimal risk exists to vulnerable populations with no prospect of direct benefit,
- There have been previously confirmed circumstances of serious or continuing non-compliance with the applicant principal investigator;

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- The REB believes that more frequent review is required for another documented reason.

4.5 Initial Review Letter

4.5.1 Throughout the process of reviewing the study, the REB will determine if revisions will need to be made by sending the investigator an "Initial Review Letter".

4.5.2 In order for the REB study to be considered as current, a response must be received within 6 months from the date of the letter, known as the "P.I. Response".

4.5.3 If a "P.I. Response" has not been submitted to the REB office within the 6 month period, then the REB will consider the study as closed without notification to the P.I.

4.5.4 In the event that the investigator would like to submit a response after the 6 month period, an extension may be granted at the discretion of the REB Chair.

4.5.5 Once the study is closed, the study file will be archived as stated in WCH REB-SOP-III-03.002.

4.5.6 In the event that an investigator wishes to re-open the study, then a new REB application submission will be required.

5.0 REFERENCES:

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2) Article 11, 13;
2. The International Conference on Harmonization Guidelines for Good Clinical Practice, Sections 3, 4.1, 4.8;
3. Ontario's Personal Health Information Protection Act (PHIPA);
4. Personal Health Information Protection and Electronic Documents Act (PIPEDA);
5. Canada Institutes for Health Research (CIHR) Best Practices for Protecting Privacy in Health Records (September 2005);
6. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.111;
7. ISO 14155 Clinical Investigation of medical devices for human subjects – Good Clinical Practice;
8. Sunnybrook Health Sciences Centre Research Ethics Board Standard Operating Procedure– *Initial Review: Criteria for Research Ethics Board Approval* (REB-SOP-IV-03.003)