Research Ethics Board Standard Operating Policies and Procedures

Investigator Qualifications and Responsibilities

SOP NO:	REB-SOP-VIII-01.003	**Revision Date:**	April 4, 2017
CATEGORY	Research Ethics Board	**Reviewed/Effective Date:**	April 4, 2017
SUB-CATEGORY	Section VIII: Responsibilities of Investigators	**Original Issue Date:**	April 1, 2014
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:

This Standard Operating Procedure (SOP) describes the qualifications and responsibilities of the Principal Investigator at Women's College Hospital (WCH) who engages in research involving human participants.

In accordance with the Tri Council-Policy Statement 2, Investigators shall submit their research proposals, including proposals for pilot studies, for Research Ethics Board (REB) review and approval of its ethical acceptability prior to the start of recruitment of participants, access to data, or collection of human biological materials. REB review is not required for the initial exploratory phase of a research project, which may involve contacting individuals or communities in order to establish research partnerships or to inform the design of a research proposal.

Research involving human participants must be conducted by individuals appropriately qualified by education, training and experience to assume responsibility for the proper conduct of the research and for the protection of human research participants. The REB must have assurance that the qualifications of investigators for the conduct of research studies are appropriate.

Investigators are required to conduct the research in compliance with applicable regulations and guidelines, and to report serious or continuing non-compliance and the status of the research at time points stipulated by the REB. The Principal Investigator must promptly notify the REB of any unanticipated problems involving risks to participants or others, (including deviations from the approved research and serious, unexpected adverse events), and of any new information that might adversely affect the safety of research participants or the conduct of the research.

2.0 DEFINITION(S):

See Glossary of Terms

3.0 RESPONSIBILITY:

This SOP applies to the REB Chair, REB members, Research Ethics Office (REO) staff, Department/Division/Program Leaders, Investigators and their study team.

The principal investigator (PI) is responsible for complying with all applicable regulations, and ensuring that:

- He/she and his/her staff members are appropriately qualified by education, training and experience to assume responsibility for the proper conduct of the research and for the protection of human research participants (http://www.womensresearch.ca/research-services/research-ethics-office/education-requirements);
- New research staff who are being added to a research study must complete and provide evidence of completion of research ethics educational requirements before they can take part in research activities;
- For all clinical trials or for research that is considered to be more than minimal risk, there is at least one appropriately qualified co-investigator or sub-investigator designated and supervised by the PI to perform critical

trial-related procedures and/or make important trial-related decisions in the event that the PI is absent, and who has agreed to be listed on the REB application and applicable delegation log;

- He/she has adequate resources to properly conduct the research and conducts the research following written standard operating procedures;
- All actual or potential conflicts of interest are declared to the REB at the time of the initial application, and as they arise;
- REB review and approval is obtained before engaging in research activities involving human participants;
- All study–related correspondence requiring formal approval or other official correspondence with the REB is signed by the principal investigator at WCH;
- All research agreements are forwarded to Manager, Grants and Contracts for review and execution prior to engaging in research involving human participants. If unsure as to the necessity of a research agreement, the Manager, Grants and Contracts should be contacted for advice;
- Clinical trials are registered in a registry that is compliant with the criteria set by the World Health Organization (WHO) or International Committee of Medical Journal Editors (ICMJE) and that the number assigned to the trial upon registration is provided to the REB and this information is communicated on the ICF;
- Express informed consent, when required, is obtained from participants prior to their enrolment into the research using the most current informed consent document approved by the REB and in accordance with applicable regulations and guidelines;
- He/she personally conducts or supervises the described investigation(s);
- The research is conducted in compliance with the approved protocol and applicable regulations, guidelines and REB SOPs;
- Any unanticipated problems involving risks to participants or others are promptly reported to REB as per the *WCH REB Internal Unanticipated Events Including Adverse Events Reporting SOP*, including protocol deviations, serious, unexpected adverse events and privacy breaches;
- Any changes in the approved research are not initiated without REB review and approval, except where necessary to eliminate an immediate hazard(s) to the participant(s);
- Premature termination or suspension of research is promptly reported to REB;
- Accurate and complete records are maintained according to applicable regulatory requirements;
- Written summaries of the study status are submitted to REB at least annually, or more frequently if required by REB, and an application for continuing review is submitted to REB prior to the expiration of REB approval;
- Any other unexpected findings or new research knowledge that could affect the risk/benefits ratio of the research are reported promptly to REB,
- The REB is notified if he/she leaves the institution (e.g. temporarily on sabbatical or permanently);
- The REB is notified immediately if his/her regulated health professional license registration or hospital privileges are suspended, restricted or revoked or should his/her qualifications otherwise no longer be appropriate;
- The REB is notified when the study is completed;

- The REB must provide with appropriate documentation for Continuing REB approval through the submission of a Request for Continuing REB Approval form completed before the date of the annual approval expiry or renewal.

4.0 PROCEDURES:

4.1 Principal Investigator Qualifications

4.1.1 The REB may request to review the Principal Investigator's current CV at any time;

4.1.2 The PI must have the authority to practice in their specialty within the institution;

4.1.3 The PI must have completed appropriate training related to requirements of conducting and overseeing research (proof of training may be requested);

4.1.4 The PI must include sufficient evidence of Departmental approval with each REB application

4.1.5 Any concerns raised in relation to the PI's qualifications to conduct the study under review will be communicated to the Investigator and must be satisfied prior to REB approval of the investigator;

4.1.6 If there are significant concerns, the PI's qualifications should be referred to the full Board at a convened meeting

4.2 Principal Investigator Qualifications for Clinical Trials Regulated by Health Canada

4.2.1 For clinical trials regulated by Health Canada, there must be a Qualified Investigator (QI). The QI is the person responsible to the sponsor for the conduct of the clinical trial at a clinical trial site, who is entitled to provide health care under the laws of the province where the clinical trial site is located and who is: (a) in the case of a clinical trial involving a drug to be used for dental purposes only, a physician or dentist and a member in good standing of a professional medical or dental association; and (b) in any other case, a physician and a member in good standing of a professional medical association

4.2.2 In the case of an Investigator-Initiated Clinical Trial Application or Investigational Testing Authorization to Health Canada, the local WCH PI applying to the REB does not need to be the QI as defined above in 4.2.1. There must, however, be a WCH PI for the clinical trial. This person must be clearly designated on the REB application (i.e. listed as a Co-Investigator). The obligations of a QI holding a CTA with Health Canada include both those of sponsor and of an Investigator.

4.3 Departmental Approval

4.3.1 The Department/Division/Program Head, by signing the REB application, confirms that:

- He/she is aware of the proposal and supports its submission for ethics review;
- Considers it to be feasible and appropriate;
- Any internal departmental requirements have been met;
- The Investigator responsible for the conduct of the study, is qualified by education, training and experience to perform his/her role in the study;
- The Investigator has sufficient space and resources to conduct this research.

5.0 REFERENCES:

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2), Article 6.11, 11.3

2. Health Canada, Division 5 Part C.05.001 of the Food and Drug Act
3. Health Canada Guidance for Clinical Trial Sponsors: Clinical Trial Applications
4. The International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (GCP), Section 1.56, 3.1.3 and Section 4
5. Sunnybrook Health Sciences Centre, REB-SOP-VIII-01.004. Investigator Qualifications and Responsibilities