1.0 PURPOSE

This standard operating policy and procedure (SOP) describes the qualifications and responsibilities of the Principal Investigator at Sunnybrook who engages in research involving human participants.

2.0 POLICY STATEMENT

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 Research Ethics Board (REB) must have assurance that the qualifications of new 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.

3.0 DEFINITIONS

Director: refers to the Director of the Clinical Studies Resource Centre who oversees the operations of the Research Ethics Office (REO) and the administrative functions of the REB.

Qualified Investigator: 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 that clinical trial site is located and who is:
(a) in the case of a clinical trial respecting 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.
Investigator Qualifications and Responsibilities

**Sponsor-Investigator**: an individual who both initiates and conducts a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a research participant. The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.

### 4.0 RESPONSIBILITY

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

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;
- 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 REB at the time of the initial application, and as they arise;
- REB review and approval is obtained before engaging in research involving human participants;
- all study-related correspondence requiring formal approval or other official correspondence with REB is signed by the principal investigator at Sunnybrook;
- the contract(s) and/or agreement(s) is forwarded to Sunnybrook Department of Legal Services for review and execution prior to engaging in research involving human participants, and if unsure as to the necessity of a contract/agreement, Legal Services will 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;
- 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 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 policies;
- any unanticipated problems involving risks to participants or others are promptly reported to REB, 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 the 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/benefit ratio of the research are reported promptly to REB;
- REB is notified if he/she leaves the institution (e.g., temporarily on sabbatical or permanently);
- REB is notified immediately if his/her medical license or hospital privileges are suspended, restricted or revoked or should his/her qualifications otherwise no longer be appropriate;
Investigator Qualifications and Responsibilities

- REB is notified when the study is completed.

The obligations of a PI holding a Clinical Trial Application with Health Canada (i.e., sponsor-investigator) include both those of a sponsor and those of a PI.

At Sunnybrook, the Department is responsible for maintaining current CVs and medical licenses of each of its Principal Investigators. The Department is also responsible for immediately advising REB should it become aware of any information that would indicate that the qualifications of the PI may no longer be appropriate.

The sponsor is responsible for ensuring that the Principal Investigator (PI) completes the Health Canada Qualified Investigator Undertaking Form.

5.0 PROCEDURES

5.1 Principal Investigator Qualifications

5.1.1 The Department/Division/Program Head is responsible for keeping a current CV of the Principal Investigator on file. In some cases (i.e. nursing) the CV is kept by Human Resources;

5.1.2 The REB may request to review the CV at any time;

5.1.3 The Department/Division/Program Head, by signing the REB application, confirms that he/she is aware of the proposal and support its submission for ethics review; considers it to be feasible and appropriate and attests that the PI responsible for the conduct of the study, is qualified by education, training and experience to perform his/her role in the study;

5.1.4 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 that clinical trial site is located and who is:
   (a) in the case of a clinical trial respecting 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.

5.1.5 In the case of an Investigator-Initiated Clinical Trial Application or Investigational Testing Authorization to Health Canada, the local Sunnybrook PI applying to the REB does not need to be the QI as defined above in 5.1.4. There must, however, be a Sunnybrook QI who meets the criteria as defined in 5.1.4) for the clinical trial. This person must be clearly designated on the REB application (i.e. listed as a Co-Investigator);

5.1.6 The PI must have the authority to practice in their specialty within the institution;
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5.1.7 The PI must have completed appropriate training regarding the requirements of conducting and overseeing research (proof of training may be requested);

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

6.0 REFERENCES

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2), Article 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 3.1.3 and Section 4.