SOP Title	Initial review Criteria for HSREB
Number.Version	404.003
Version Date	05/10/2016

Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Research Ethics		05/11/2016
Dr. Joseph Gilbert Chair, Health Sciences Research Ethics Board	Joseph Gilbert	05/11/2016

1. PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the minimum requirements of research proposals involving human participants for approval by the Health Sciences Research Ethics Board (HSREB), independent of the review pathway (Full Board or via delegated review).

2. GENERAL POLICY STATEMENT

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

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

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

3. RESPONSIBILITY

This SOP applies to the HSREB Chair, Vice-Chair(s), HSREB members, and Office of Human Research Ethics (OHRE) staff.

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

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

4. DEFINITIONS

See Glossary of Terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. Minimal Criteria for Approval of Research

In order for a research study to receive HSREB approval, during its review, the HSREB takes the following into consideration:

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

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

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

5.1.4. Risks to participants are minimized by:

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

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

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

5.1.7. There are sound scientific and ethical reasons for excluding classes of persons who might benefit from research:

- 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 includes both women and men when appropriate, and does not arbitrarily exclude the participation of persons of reproductive ages;

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

5.1.9. The amount and method of payment to participants to assure there is no coercion or undue influence and that information regarding payment to participants, including method, amounts and schedule is provided to participants as applicable;

5.1.10. 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 HSREB may approve a consent procedure that does not include, or which alters (e.g. deferral), some or all of the elements of informed consent, or waive the requirement to obtain informed consent.

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

5.1.12. The informed consent process is clearly described in the application;

5.1.13. There are provisions for on-going data and safety monitoring, as evidence by a data safety monitoring plan (DSMP), that are appropriate to the size, complexity, phase, and level of risk of the study. The HSREB may recommend the use of a data and safety monitoring board (DSMB) to enhance participant protection;

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

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

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

5.1.17. The research has been submitted to Health Canada if applicable, and the Health Canada No Objection Letter has been issued;

5.1.18. The research study has been registered v registered on a publicly accessible clinical trial registry and the registration number has been submitted to the HSREB prior to the recruitment of the first participant.

5.2. **Additional Criteria**

5.2.1. Studies proposing access to or collection of personal health information require consideration of additional items to protect the privacy of the personal health information. Therefore the HSREB must find that;

- Authorization is obtained from participants or their legally authorized representative for the collection, use or disclosure of their personal health information, or the HSREB has approved a waiver of such authorization;
- The personal health information should 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).

5.3. **Minimal Criteria for Approval to Conduct the Research**

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

5.3.1. The application has been submitted by the principal investigator;

5.3.2. The investigator has the qualifications to conduct the research as attested by the Institutional Sign Off (ISO) issued by the London Health Sciences Centre (LHSC);

5.3.3. Any potential conflicts of interest are managed to prevent any compromises to the safety or well-being of participants or the integrity of the data;

5.3.4. The recruitment methods respect the privacy of individual participants;

5.3.5. The letters of information and form(s) accurately explains the research and contains the required elements;

5.3.6. Informed consent process is clearly described in the application;

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

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

5.3.9. Clinical Trials are registered with a recognized public registry and the registration number provided to the HSREB.

5.4. **Length of Approval Period**

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

5.4.2. The HSREB may require review more often than annually when there is a high degree of risk to participants relative to the population,

5.4.3. The HSREB 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 instances of serious or continuing non-compliance with the applicant principal investigator,
- The HSREB believes that more frequent review is required.

6. REFERENCES

6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2);
6.2. The International Conference on Harmonization Guidelines for Good Clinical Practice, Sections 3, 4.1, 4.8;
6.3. Ontario's Personal Health Information Protection Act (PHIPA);
6.4. Personal Health Information Protection and Electronic Documents Act (PIPEDA);
6.5. Canadian Institutes for Health Research (CIHR) Best Practices for Protecting Privacy in Health Research (September 2005);
6.6. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.111;
6.7. ISO 14155 Clinical investigation of medical devices for human subjects – Good Clinical Practice.

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyy
404.001	Original	01/20/2014
404.002	Updated Erika Basile position Added section 5.1.18 Revised section 5.3.2 for clarification Minor administrative changes for clarity	05/22/2014
404.003	Minor administrative corrections for clarity	05/10/2016