SOP Title	**Initial review Criteria for NMREB**
Number.Version	N404.002
Effective Date	09/06/2018

Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Office of Human Research Ethics		2019-02-26
Professor Randal Graham Chair, Non-Medical Research Ethics Board		2019-03-06

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 Non-Medical Research Ethics Board (NMREB), 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 NMREB 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 NMREB approval of the research is based on assessment of a complete application package. The NMREB may consult the Investigator for additional information as necessary.

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

3. RESPONSIBILITY

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

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

The NMREB Chair or designee is responsible for ensuring the NMREB 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 NMREB approval, during its review, the NMREB takes the following into consideration:

5.1.1. The research will produce generalizable knowledge

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

5.1.3. Risks to participants are minimized by:

- using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk;

5.1.4. 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 NMREB 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 NMREB should not consider long-range effects of applying the knowledge gained in the research;

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

5.1.6. 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,
- The research includes both women and men when appropriate, and does not arbitrarily exclude the participation of persons of reproductive ages;

5.1.7. 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 NMREB review process to protect the rights and welfare of these participants;

5.1.8. 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;

5.1.9. 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 NMREB 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.

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

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

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

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

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

5.2. **Additional Criteria**

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

- Authorization is obtained from participants or their legally authorized representative for the collection, use or disclosure of their personal information, or the NMREB has approved a waiver of such authorization;
- The personal information is handled in accordance with Western University's institutional policies and procedures pertaining to data security and confidentiality (see Data Security and Confidentiality Guidance Document).

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

In order to receive approval to participate in research, the NMREB 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) (if applicable);

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;

5.4. **Length of Approval Period**

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

5.4.2. The NMREB 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 NMREB 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 NMREB 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. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.111;

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyy
N404.001	Original	07/07/2016
N404.002	Administrative Corrections	09/06/2018