SOP Title	**NMREB Investigator Qualifications and Responsibilities**
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Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Research Ethics		2019-02-26
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1. PURPOSE

This Standard Operating Procedure (SOP) describes the qualifications and responsibilities of the Principal Investigator at Western University who engages in research involving human participants.

2. GENERAL 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 Non-Medical Research Ethics Board (NMREB) 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 NMREB. The Principal Investigator must promptly notify the NMREB 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. RESPONSIBILITY

This SOP applies to the NMREB Chair, Vice-Chair(s), NMREB members, and Office of Human Research Ethics (OHRE) 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 NMREB at the time of the initial application, and as they arise;

- NMREB review and approval is obtained before engaging in research involving human participants;
- all study-related correspondence requiring formal approval or other official correspondence with NMREB is signed by the principal investigator at Western University;
- the contract(s) and/or agreement(s) is forwarded to Western University's Research Development and Services Contracts Office 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;
- 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 NMREB 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 NMREB policies;
- any unanticipated problems involving risks to participants or others are promptly reported to NMREB, including protocol deviations, serious, unexpected adverse events and privacy breaches;
- any changes in the approved research are not initiated without NMREB 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 NMREB;
- accurate and complete records are maintained according to applicable regulatory requirements;
- written summaries of the study status are submitted to NMREB at least annually, or more frequently if required by the NMREB, and an application for continuing review is submitted to the NMREB prior to the expiration of NMREB approval;
- any other unexpected findings or new research knowledge that could affect the risk/benefit ratio of the research are reported promptly to NMREB;
- the NMREB is notified if he/she leaves the institution (e.g., temporarily on sabbatical or permanently);
- the NMREB is notified immediately if his/her qualifications are no longer appropriate, applicable;
- the NMREB is notified when the study is completed;
- At Western University and its affiliates, the Department is responsible for maintaining current *Curriculum Vitae's* (CVs) and licenses of each of its Investigators. The Department is also responsible for immediately advising the NMREB should it become aware of any information that would indicate that the qualifications of the Investigator may no longer be appropriate.

4. DEFINITIONS

See glossary of terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. **Principal Investigator Qualifications (Western University PIs)**

5.1.1. The Department/Division/Program Head is responsible for ensuring a current CV's of the Investigator is on file. In some cases the CV may be kept by Human Resources;

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

5.1.3. The Investigator must have the authority to practice in their specialty within the institution;

5.1.4. The Investigator must have completed appropriate training regarding the requirements of conducting and overseeing research (proof of training may be requested);

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

6. REFERENCES

6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2) Article 11.3;

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyy
N801.001	Original	07/08/2016
N801.002	Update to NMREB Chair & Administrative Corrections	05/11/2018