



SOP Title	HSREB Investigator Qualifications and Responsibilities
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Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Research Ethics and Compliance		20 Jan 2022
Dr. Philip Jones Chair, Health Sciences Research Ethics Board		27 Jan 2022

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 Health Sciences Research Ethics Board (HSREB) 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 HSREB. The Principal Investigator must promptly notify the HSREB 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 HSREB Chair, Vice-Chair(s), HSREB 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;
- 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, and who has agreed to be listed on the HSREB 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 HSREB at the time of the initial application, and as they arise;
- HSREB review and approval is obtained before engaging in research involving human participants;
- all study-related correspondence requiring formal approval or other official correspondence with HSREB is signed by the principal investigator at the University of Western Ontario;
- the contract(s) and/or agreement(s) is forwarded to the University of Western Ontario's Research Development and Services Contracts Office or Lawson Health Research Institute 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;
- 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 HSREB;
- 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 HSREB 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 HSREB policies;
- any unanticipated problems involving risks to participants or others are promptly reported to HSREB, 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 HSREB;
- accurate and complete records are maintained according to applicable regulatory requirements;
- written summaries of the study status are submitted to HSREB at least annually, or more frequently if required by the HSREB, and an application for continuing review is submitted to the HSREB prior to the expiration of HSREB approval;
- any other unexpected findings or new research knowledge that could affect the risk/benefit ratio of the research are reported promptly to HSREB;
- the HSREB is notified if he/she leaves the institution (e.g., temporarily on sabbatical or permanently);
- the HSREB 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;
- the HSREB is notified when the study is completed;
- At the University of Western Ontario and its affiliates, the Department is responsible for maintaining current *Curriculum Vitae*'s (CVs) and medical licenses of each of its Investigators. The Department is also responsible for immediately advising the HSREB 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 (University of Western Ontario 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 HSREB may request to review the CV at any time;
- 5.1.3. 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 is 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;
- 5.1.4. In the case of an Investigator-Initiated Clinical Trial Application or Investigational Testing Authorization to Health Canada, the local Western University Investigator applying to the HSREB does not need to be the QI as defined above in 5.1.4. There must, however, be a University of Western Ontario QI for the clinical trial. This person must be clearly designated on the HSREB application (i.e. listed as a Co-Investigator). The obligations of a QI holding a CTA with Health Canada (i.e. sponsor-investigator) include both those of a sponsor and of an Investigator;
- 5.1.5. The Investigator must have the authority to practice in their specialty within the institution;
- 5.1.6. The Investigator must have completed appropriate training regarding the requirements of conducting and overseeing research (proof of training may be requested);
- 5.1.7. 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 REB approval of the investigator.

5.2. Principal Investigator Qualifications (Lawson Health Research Institute Investigator's)

- 5.2.1. The Department/Division/Program Head is responsible for ensuring a current CV of the Investigator is on file. In some cases the CV may be kept by Human Resources;
- 5.2.2. The HSREB may request to review the CV at any time;
- 5.2.3. Lawson Health Research Institute confirms, by completing institutional sign off, 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 Investigator is responsible for the conduct of the study, is qualified by education, training and experience to perform his/her role in the study;
- 5.2.4. 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;

5.2.5. In the case of an Investigator-Initiated Clinical Trial Application or Investigational Testing Authorization to Health Canada, the local University of Western Ontario Investigator applying to the HSREB does not need to be the QI as defined above in 5.1.4. There must, however, be a University of Western Ontario QI for the clinical trial. This person must be clearly designated on the HSREB application (i.e. listed as a Co-Investigator). The obligations of a QI holding a CTA will Health Canada (i.e. sponsor-investigator) include both those of a sponsor and of an Investigator.

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

5.2.7. The Investigator must have completed appropriate training regarding the requirements of conducting and overseeing research. Proof of training is overseen by Representatives of Lawson Quality Assurance Education Program;

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

6. REFERENCES

- 6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2);
- 6.2. The International Conference on Harmonization Guidelines for Good Clinical Practice, Section 1.56, 3.1.3 and Section 4;
- 6.3. Health Canada, Division 5, Part C.05.001 of the Food and Drug Act;
- 6.4. Health Canada Guidance for Clinical Trial Sponsors: Clinical Trial Applications;

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
801.001	Original	01/21/2014
801.002	Revisions to guidelines for correctness	05/29/2014
801.003	Minor administration revisions for clarity	05/10/2016
801.004	Minor administrative corrections	01/27/2022