

Title	Researcher Qualifications and Responsibilities
SOP Code	801.002
Effective Date	01-July-2016

Site Approvals

Name and Title (typed or printed)	Signature	Date dd/mmm/yyyy
Karine Morin Executive Director, Platforms	<i>original signed</i>	effective 01-July-2016

1.0 PURPOSE

This standard operating procedure (SOP) describes the qualifications and responsibilities of the Researcher who engages in research involving human participants.

2.0 SCOPE

This SOP pertains to Research Ethics Boards (REB) that review human participant research in compliance with applicable regulations and guidelines.

3.0 RESPONSIBILITIES

All Researchers, REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

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

REB must have assurance that the qualifications of new Researchers, for the conduct of research, are appropriate.

Researchers are required to conduct the research in compliance with applicable regulations and guidelines, and to comply with all REB policies.

5.1 Researcher Qualifications

- 5.1.1 The Researcher must make available to the REB his/her current CV and medical license number (if applicable) and his/her relevant training and experience, in sufficient detail for the REB to make an objective judgment regarding the Researcher's qualifications, if necessary;
- 5.1.2 If applicable, the Researcher must be a physician with a specialty qualification in their field and with current professional qualifications entitling them to provide health care under the applicable laws;
- 5.1.3 The Researcher must have completed appropriate training regarding the requirements of conducting and overseeing research;
- 5.1.4 If applicable, all specified Organizational Officials must approve the application to the REB;
- 5.1.5 The organizational approver's signature attests that:
 - He/she is aware of the proposal and supports its submission for REB review,
 - The application is considered to be feasible and appropriate,
 - Any internal requirements have been met,
 - The Researcher is qualified and has the experience and expertise to conduct this research,
 - The Researcher has sufficient space and resources to conduct this research;
- 5.1.6 Any concerns raised in the REB review of the Researcher's qualifications will be communicated to the Researcher and must be satisfied prior to REB approval of the application.

5.2 Researcher Responsibilities

- 5.2.1 The Researcher is responsible for complying with the decisions and responsibilities set out by the REB. In addition, it is the Researcher's responsibility to comply with all applicable regulations and ensure that (if applicable):

- 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 protection of human research participants,
- He/she has adequate resources to properly conduct the research and conducts the research following written SOPs,
- All real, potential, or perceived conflicts of interest are declared to the REB at the time of the initial application, and as they arise,
- The REB review and approval is obtained before engaging in research involving human participants,
- All necessary documentation is signed by the responsible Researcher, as applicable,
- Informed consent, when required, is obtained from participants in accordance with applicable regulations prior to their enrollment into the research, and using the most current informed consent document(s) approved by the REB (as applicable),
- He/she personally conducts or supervises the described investigation(s),
- The research is conducted in compliance with the approved research and applicable reporting criteria are reported to the REB, including 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 reported to the REB;
- Accurate and complete records are maintained according to applicable regulatory requirements,
- Written summaries of the research status are submitted to the REB at least annually, or more frequently if required by the REB, and an application for continuing review is submitted to the REB prior to the expiration of REB approval,
- Any other unexpected finding or new research knowledge that could affect the risk/benefit ratio of the research is reported to the REB,
- The REB is notified if there is a change in Researcher,
- The REB is notified immediately if his/her medical or dental license or hospital privileges are suspended, restricted or revoked (if applicable) or should his/her qualifications otherwise no longer be appropriate,
- The REB is notified when the research is complete;

Note: (If applicable) the obligations of a Researcher holding a Clinical Trial Application (CTA) with Health Canada (i.e. Sponsor-Researcher) include both those of a sponsor and those of a Researcher.

5.2.2 The organization is responsible for maintaining current CVs and medical licenses (if appropriate) for each of its Researchers. The organization is responsible for immediately advising the REB should it become aware of any information that would indicate that the qualifications of the Researcher may no longer be appropriate.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP801.001	01 July 2016	Original version
SOP801.002	01 July 2016	Version 2 - no changes