TITLE	**801: Researcher Qualifications and Responsibilities**
SCOPE	All health research submitted to the Health Research Ethics Board (HREB) operating under the direct authority of the Health Research Ethics Authority (HREA)
APPROVAL AUTHORITY	Ethics Director
EFFECTIVE DATE	April 2024

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 DEFINITIONS

See the Glossary of Terms.

3.0 RESPONSIBILITIES

All Researchers, HREB members and Research Ethics Office (REO) Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 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 HREB 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 legislation, regulations and guidelines and to comply with applicable HREB policies.

4.1 Researcher Qualifications

4.1.1 Researchers will provide the HREB with a current Curriculum Vitae (CV), containing professional license number (if applicable) as well as relevant training and experience, in sufficient detail for the HREB to make an objective judgment regarding the Researcher's qualifications.

4.1.2 If required by federally regulated clinical trials, the Researcher must be a physician with a specialty qualification in the relevant field and current professional qualifications to provide health care under the applicable laws.

4.1.3 The Researcher will have completed appropriate training regarding the requirements of conducting and overseeing research. Any concerns raised in the HREB review of the Researcher's qualifications will be communicated to the Researcher and must be satisfied prior to HREB approval of the application.

4.1.4 Students are required to submit a Supervisor Attestation Form with their research application.

4.1.5 Supervisors' signatures attest that they:

- approve of the study design;
- approve of the study as written;
- have read the HREB application and verify that the information provided is accurate and complete; and
- have provided the REO with a certificate of completion of the online TCPS2 CORE tutorial.

4.16 Any concerns raised in the HREB review of the Researcher's qualifications will be communicated to the Researcher and must be satisfied prior to HREB approval of the application.

4.2 Researcher Responsibilities

4.2.1 Researchers are responsible for complying with the decisions and responsibilities set out by the HREB, as well as all applicable regulations. If applicable, they will ensure that:

- they accept responsibility for conducting or supervising all investigations described in the application;
- they and all study 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;
- there are adequate resources to properly conduct the research and the research is conducted following written SOPs;
- all real, potential, or perceived conflicts of interest are declared to the HREB at the time of the initial application, and as they arise;
- HREB 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 HREB (as applicable);

- the research is conducted in compliance with the approved research, and applicable reporting criteria are reported to the HREB, including deviations, serious, unexpected adverse events and privacy breaches;
- any changes in the approved research are not initiated without HREB 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 HREB;
- accurate and complete records are maintained according to applicable regulatory requirements;
- written summaries of the research status are submitted to the HREB at least annually, or more frequently if required by the HREB, and an application for continuing review is submitted to the HREB prior to the expiration of HREB approval;
- any other unexpected finding or new research knowledge that could affect the risk/benefit ratio of the research is reported to the HREB;
- the HREB is notified if there is a change in Researcher;
- the HREB is notified immediately if Researcher's professional or hospital privileges are suspended, restricted or revoked (if applicable) or should their qualifications otherwise no longer be appropriate; and
- the HREB is notified when the research is complete.

Note: 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.

4.2.2 The Researcher is responsible for maintaining a current CV and professional license, as applicable. If applicable, the Researcher's organization is responsible for immediately advising the HREB should it become aware of any information that would indicate that the qualifications of the Researcher may no longer be appropriate.

5.0 REFERENCES

Health Canada Guidance for Industry, Good Clinical Practice: Consolidated Guideline, ICH Topic E6(R2), Notice - Interim Implementation of International Council for Harmonisation (ICH) Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) - Canada.ca

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans: https://ethics.gc.ca/eng/documents/tcps2-2022-en.pdf