RD0200 – RESEARCHER QUALIFICATIONS AND RESPONSIBILITIES

Interior Health would like to recognize and acknowledge the traditional, ancestral, and unceded territories of the Dãkelh Dené, Ktunaxa, Nlaka'pamux, Secwépemc, St'át'imc, Syilx, and Tŝilhqot'in Nations, where we live, learn, collaborate and work together.

Interior Health recognizes that diversity in the workplace shapes values, attitudes, expectations, perception of self and others and in turn impacts behaviors in the workplace. The dimensions of a diverse workplace includes the protected characteristics under the human rights code of: race, color, ancestry, place of origin, political belief, religion, marital status, family status, physical disability, mental disability, sex, sexual orientation, gender identity or expression, age, criminal or summary conviction unrelated to employment.

1.0 PURPOSE

To describe the qualifications and responsibilities of a Researcher engaging in Research involving human participants within the jurisdiction of Interior Health (IH) that are required to assume responsibility for the conduct of the Research and for the protection of human Research participants.

2.0 DEFINITIONS

TERM	DEFINITION
Patient	A person who has experience with the health care system and/or personal experience of a health issue, including family, friends and informal caregivers.
Patient-oriented Research (POR)	Research that engages Patients as partners and focuses on Patient-identified priorities with the goals of improving Patient experiences, health outcomes and the health system.
Principal Investigator (PI)	The leader of a Research team who is responsible for the ethical conduct of the Research, and for the actions of any member of the Research team in relation to the Research.
Qualified Investigator (QI)	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: • 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;

RD0200 – RESEARCHER QUALIFICATIONS AND RESPONSIBILITIES

	• In any other case, a physician and a member in good standing of a professional medical association. There can only be one QI per study per Canadian study site. (Definition from Health Canada, Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects and specific to Research conducted under this regulation).
Research	An undertaking to extend knowledge through a disciplined inquiry or systematic investigation.
Researcher	A person conducting a disciplined inquiry and responsible for the conduct of the Research.

3.0 POLICY

3.1 Research involving human participants must be conducted by individuals appropriately qualified by education, training, and experience to ensure the responsible conduct of Research and the protection of human Research participants.

3.2 The IH Research Ethics Board (IH REB) and IH Research Department (IH RD) must have assurance that the qualifications of the Researcher(s) are appropriate for each proposed Research project that involves IH.

The IH REB or IH RD communicates concerns regarding the Researcher's qualifications identified during the respective IH REB ethical review or the IH RD approval process to the Researcher and must be satisfied prior to the certificate of Institutional Approval to Conduct Research being granted.

3.3 The Researcher must conduct the Research in compliance with all applicable legislation, regulations, and IH policies.

4.0 PROCEDURES

4.1 Researcher Qualifications

4.1.1 The Researcher makes available to the IH REB and IH RD, their current curriculum vitae (CV) and their relevant training and experience, in

sufficient detail for IH to make an objective judgment regarding the Researcher's qualifications, if necessary.

4.1.2 The Researcher completes appropriate training regarding the requirements of conducting and overseeing Research.

4.1.3 The physician or dentist conducting Research as a Qualified Investigator per Health Canada regulations must be a physician or dentist with a specialty qualification in the field and with current professional qualifications entitling them to provide health care under the applicable laws. The physician Researcher may also be required to provide a copy of their medical license number.

4.1.4 The patient or community member engaged as a Researcher in Patient–oriented Research is considered an expert in their own health care, or that of a family member, friend, or person in their care, and has a unique perspective from their lived experience.

The Patient or community member as Researcher may be involved in priority-setting and decision-making related to Research, supporting a more comprehensive understanding of the Patient experience of care, and to collaboratively identify and explore gaps in evidence.

The Patient or community member engaged in Research receives training, orientation and support as required, both before and throughout the Research process.

4.1.5 The Researcher with no current affiliation with IH may apply to the IH Research Department for affiliated researcher status prior to conducting Research within IH.

4.1.6 A student Researcher acts as the PI only if they are affiliated as a permanent employee with IH. If the student has no employee affiliation with IH, their academic supervisor must act as the PI.

4.2 Researcher Responsibilities

4.2.1 The Researcher complies with the decisions and responsibilities set out by the IH REB and IH RD.

4.2.2 The Researcher complies with all applicable regulations and IH policies and ensures that they:

RD0200 – RESEARCHER QUALIFICATIONS AND RESPONSIBILITIES

- Commit to high ethical standards and values, and demonstrates awareness of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. A Researcher conducting above-minimal risk Research in IH must have completed TCPS2 CORE training. A Researcher conducting minimal-risk Research is expected to know these standards, though proof of completion of the tutorial is not mandatory;

- Qualify by education, training and experience to assume responsibility for the conduct of the Research and for the protection of human Research participants;

- Have resources to conduct the Research following written IH policies and Standard Operating Procedures (SOPs);

- Declare all real, potential, or perceived conflicts of interest to the IH REB and IH RD at the time of the initial application, and as they arise;

- Obtain IH REB approval and IH operational approval, and complete any other required contracts, in order to receive a Certificate of Institutional Approval before the Research commences;

- Conduct Research using identifiable information of Patients, clients and residents per IH policy *RD0500 Information Requests for Research* and applicable IH information privacy and security policies;

- Sign all necessary documentation;

- Obtain informed consent, when required, 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 IH REB;

- Conduct Research in compliance with the approved protocol and any changes are not initiated without IH REB review and approval, except where necessary to eliminate an immediate hazard(s) to the participant(s);

- Report serious adverse events, serious unexpected adverse events and protocol deviations to the IH REB, as per policy RR0900 Safety and Adverse Events Reporting;
- Maintain accurate and complete records according to applicable regulatory requirements;
- Submit written summaries of the Research status to IH REB at least annually, or more frequently if required;
- Submit an ethical approval renewal application prior to the expiration of IH REB approval;
- Report any other unexpected finding or new Research knowledge that could affect the risk/benefit assessment of the Research to the IH REB;
- Notify the IH REB if there is a change in Researcher or Research team members;
- Notify the IH REB when the Research is complete.

4.2.3 The Primary Investigator is responsible for all items in 4.2.1 and in addition:

- Ensures that all Research team 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;
- Conducts or supervises the described investigation(s);
- Reports any premature termination or suspension of the Research project by a Sponsor, Health Canada, or other authorized agency to the IH REB.

4.2.4 If the Researcher holds a Clinical Trial Application (CTA) with Health Canada (i.e., Sponsor-Researcher) their obligations include both those of a Sponsor and those of a Researcher.

4.3 Research Department Responsibilities

4.3.1 Maintains current CVs and professional licenses (if applicable) for each of its Researchers and immediately notifies the IH REB when the

Research Department becomes aware of information that indicates that the qualifications of the Researcher are no longer appropriate.

5.0 REFERENCES

- BC SUPPORT Unit. (2018). *Glossary of Terms*.
- Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2022.
- Panel on Research Ethics. (2022).*Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, CORE Tutorial*.
- Health Canada, Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects, (Schedule 1024), February 11, 2022.
- Interior Health. (2023). *Clinical Research Glossary of Terms*.
- Interior Health. (2023). Administrative Policy Manual: *AR0400 Privacy and Management of Confidential Information*.
- Interior Health. (2023). Research Department Policy Manual: *RD0300 Operational Approval to Conduct Research*.
- Interior Health. (2023), Research Department Policy Manual: *RD0500 Information Requests for Research*.
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), ICH Harmonised Guideline, Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice, E6(R2), November 9, 2021.
- N2 Network of Networks. (2023). Standard Operating Procedure 801.002: *Researcher Qualifications and Responsibilities*.
- UBC Office of Research Ethics. (2018). Standard Operating Procedure 801: *Responsibilities of Investigators*.