



Interior Health

Every person matters

March 25, 2020

To: IH Research Stakeholders
From: Dr. Deanne Taylor, Corporate Director, Research
Interior Health
Re: Coronavirus and Research with Human Participants

During this time we must follow the directives relating to the COVID-19 pandemic, and be aware that these directives will change to accommodate the rapidly evolving situation. Efforts to reduce, minimize or eliminate risks related to research participants and the public are critical at this point, and we must minimize any burden that clinical trials and clinical research activity can create for our health care system. We will also look to mitigate risks for health services and patient-orientated research requiring travel, direct contact or committee discussion. In collaboration with sponsors and supporting institutions, teams will explore transitions to remote learning, data collection and focus groups wherever feasible.

Key principles:

1. Safety of our research participants, their families and staff.
2. Limit excessive use of resources within Interior Health given the risks involved with reduced staff capacity and increasing demands on our health care system.
3. Minimize the potential spread of COVID-19.
4. Limit adverse impact on the integrity of ongoing trials.

Guidance is subject to change as the situation evolves. We will review and advise on any changes on a regular basis.

Clinical trials and clinical research operations at IH sites

Effective immediately, IH is suspending the initiation of new clinical trials/clinical research projects and halting recruitment for new and ongoing clinical trials/clinical research studies until further notice. We are doing this in consideration of continuity of care and participant and staff safety.

Enrolment into clinical trials and clinical research studies that are part of essential clinical care, projects related to the COVID-19 pandemic, or those that have significant cost or time-related implications will be assessed on a case-by-case basis. Please contact the Research Department at Research@interiorhealth.ca to discuss further.

We recognize that some ongoing clinical trials / clinical research studies require important safety monitoring and/or on-site visits that are critical to the participant's clinical care, and therefore encourage investigators to use good judgment and consider the level at which this is appropriate for each ongoing protocol and patient participant. Wherever possible, patient visits will be conducted virtually using telephone interviews. Safety monitoring conducted out-of-

window due to participant risk-level or clinical capacity will be considered for reasonable protocol deviations with appropriate reporting and documentation under the oversight of the Qualified Investigator and in communication with sponsor.

Effective immediately, the following actions are to be instituted in regards to ongoing clinical trials and clinical research studies:

1. **Study sponsor scheduled monitoring visits** may be permitted in IH facilities, but outside of clinical settings providing direct patient care. Monitors with a history of U.S. or international travel within 14 days are not permitted into any IH facility. Remote monitoring and virtual appointments must be conducted where possible (e.g. meeting with the Principle Investigator or other staff). Similarly, site initiation visits requiring study sponsor travel and in-person start-up will be postponed. Studies will be re-assessed on a trial-by-trial basis for the feasibility of conducting a virtual initiation.
2. **Clinical trials / clinical research** staff should contact clinical trials / clinical research participants by phone beforehand to actively screen for symptoms of or exposure to COVID-19 infection prior to their appointments at the clinical research unit. (i.e. study-specific imaging, lab work or medical follow up).
3. **Timely and comprehensive communication** with study sponsors, when applicable, should be maintained to inform them of any protocol deviations or interruption of accrual activities. Prior to the visits, attempts should be made to contact and screen monitors and site initiation staff attending a non-clinical IH facility to obtain a travel history and communicate evolving health authority policy.
4. Please be mindful of any **FDA or Health Canada directives** that may be affecting the conduct of specific clinical trials when applicable.

Health research

At this time, we will support health research that does not impact operations. Please move to telephone interviews to align with social distancing. Postpone any in-person gatherings such as focus groups or knowledge translation events during this time. For any questions regarding existing operational approvals, please contact the IH Research Department at Research@interiorhealth.ca to discuss further.

Research ethics considerations

In relation to practical aspects where protocol deviations may be necessary due to COVID-19, while the Tri-Council Policy Statement (TCPS2) typically requires review and approval of modifications prior to implementation, "changes that are necessary to eliminate an immediate risk(s) to the participants may be implemented as needed, but must be reported to the Research Ethics Board (REB) at the earliest opportunity" (*Article 6.15*) at researchethics@interiorhealth.ca. The REB will temporarily extend to researchers 10 days to submit the amendment to the REB.

In relation to FDA regulated trials, *21 CFR 56.108(a)(4)* similarly allows for modification without prior approval "where necessary to eliminate apparent immediate hazards to the human subjects," and again, these changes must be reported to the REB at researchethics@interiorhealth.ca at the earliest opportunity.

We ask that any Post Approval Activities (PAAs) or e-mails sent to the REB that relate to issues or queries relating to COVID-19 are named accordingly so that they can be more easily tracked. For example, the PAA nickname should include "COVID-19" or the e-mail subject line should

include “COVID-19”. In all cases, accurate and detailed documentation of the circumstances surrounding any alterations or amendments is extremely important.

If you are submitting a new research project directly related to COVID-19, please contact the REB at researchethics@interiorhealth.ca to discuss and inform your regional medical director or contact the IH Research Department for support in locating the correct operations individual to contact at Research@interiorhealth.ca.

The REB will continue to review and work with Principle Investigators to bring new minimal-risk research applications to a state of readiness for approval, but only for those minimal-risk studies that adhere to social distancing and do not require IH operational approval.

We recognize the impact this will have on our research staff and their work. However, our decision is consistent with many of our peer organizations, as well as with the current escalation of school and other business closures. We will continue to assess the situation on a real-time basis and prepare for scenarios that allow restoration of research activity as soon as possible.

For questions and concerns relating to health research, clinical trials and clinical research activities, please contact:

Dr. Deanne Taylor
Corporate Director, Research
E: Deanne.Taylor@interiorhealth.ca

For IH REB, please contact:

Sandra Broughton, MSc
Chair, Research Ethics Board
E: Sandra.Broughton@interiorhealth.ca