IMPORTANT COVID-19 NOTICE

CLINICAL TRIALS AND HEALTH RESEARCH OPERATIONS AT ISLAND HEALTH

Date: March 20, 2020
To: Island Health Research Community
From: Cindy Trytten, Director, Research

Island Health is working in partnership with the BC Ministry of Health and the BC Centre for Disease Control to respond to the COVID-19 pandemic. BC declared a public health emergency on March 17th and a provincial state of emergency on March 18th. We are actively following new directives that will continue to change as the situation evolves. Island Health is focused on reducing risks for research participants and the public, and on proactively ensuring that Island Health and health system resources are prioritized and available to fully respond to the public health emergency as it develops.

Our key principles are:

1. Ensuring the safety of our research participants, their families and staff.
2. Reprioritizing Island Health resources in readiness to respond to the developing public health emergency.
3. Minimizing the potential spread of COVID-19.
4. Limiting adverse impact on the integrity of ongoing trials.
5. Monitoring the situation as it evolves and advising on any changes on a regular basis. As such, this guidance is subject to change.

Clinical Trials and Clinical /Health Research at Island Health

Until further notice, with consideration for continuity of care and participant and staff safety, Island Health is suspending the review and initiation of new clinical trials and clinical/health research projects, with the *exception of those related to COVID-19.* In addition, recruitment into existing trials or research studies are suspended. Initiation of and enrollment into clinical trials and clinical research studies that are a part of **essential care or that have significant cost or time-related implications** will be assessed, in cooperation with Sponsor where Island Health resources permit, on a case-by-case basis. Please see below for the appropriate contact(s) to discuss further.

We recognize that some ongoing clinical trials and clinical research studies require important safety monitoring by Investigators and Study Nurses and/or on-site visits that are critical to the participant's clinical care. We therefore encourage investigators to use good judgment and consider the level at which this is appropriate for each protocol and participant.

The following policies and guidelines of Island Health will apply to ongoing studies, effective immediately:

1. All visitors to Island Health sites are being restricted to one immediate family member or support person;
2. Study sponsor on-site monitoring visits must be deferred until further notice and replaced by remote monitoring and virtual appointments (e.g. meeting with the Principal Investigators or other staff);
3. For any clinical trial visits that continue, based on a case-by-case risk assessment by Principal Investigators responsible for medical oversight, participants must be actively screened for symptoms of or exposure to COVID-19 prior to their appointments;
4. Good communication with study Sponsors, when applicable, should be maintained to inform them of any protocol deviations, interruption of enrollment, or postponed startup of new studies.
5. Any FDA or Health Canada directives that may affect the conduct of specific clinical trials must be followed, when applicable.

Existing Studies

Changes to existing studies will be necessary due to COVID-19 measures. The Tri-Council Policy Statement (TCPS2) typically requires review and approval of modifications prior to implementation, however "*changes that are necessary to eliminate an immediate risk(s) to the participants may be implemented as needed, but must be reported to the REB at the earliest opportunity" (Article 6.15).* 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."* Again, these changes must be reported to the REB at the earliest opportunity and duly documented in the study files, in addition to the details related to conversations with participants who are impacted as part of the ongoing informed consent process.

All existing studies, irrespective of whether or not they are impacted by the COVID-19 response, will still require ongoing reporting to the REBs as per the existing research ethics approval requirements.

COVID-19 Notifications and New Applications

Any Post-Approval Activities (PAAs) or e-mails sent to the REB that relate to COVID-19 must be named accordingly so that they can be more easily tracked and actioned. For example, 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 to discuss. For OPERATIONAL questions and concerns relating to clinical trials and clinical research activities, please contact the individuals listed below.

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

For OPERATIONAL questions and concerns related to clinical trials and clinical research activities, please contact:

Cindy Trytten
Director, Research
Email: Cindy.Trytten@viha.ca

Dawn Waterhouse
Research Business Manager
Email: Dawn.Waterhouse@viha.ca

For RESEARCH ETHICS questions or concerns, please contact:

Sarah Bennett
Manager, Research Ethics and Compliance
Elizabeth.Bennett@viha.ca

For more information and updates related to COVID-19, please visit:

- Island Health
- Health Canada
- Food and Drug Administration
- Clinical Trials BC: COVID-19