

### **IMPORTANT COVID-19 NOTICE**

# NON-COVID RESEARCH AT ISLAND HEALTH: REQUESTS FOR EXEMPTIONS TO CONTINUE OR AMEND EXISTING RESEARCH

**Date: April 3, 2020** 

To: Island Health Research Community From: Cindy Trytten, Director, Research

On March 20, Island Health issued a <u>notice</u> of suspension of the review, initiation, and conduct of non-COVID-19 related clinical trials and clinical/health research projects.

Ongoing trials and clinical research studies that require important safety monitoring by Investigators and Study Nurses and/or on-site visits that are critical to the participants' clinical care are the exception and require the Principal Investigators responsible for medical oversight to actively screen (and document in the study records) the absence of symptoms of, or potential exposure to, COVID-19 in participants prior to attending such visits.

Inquiries continue to be received by study teams regarding potential continuation of, or amendments to, existing research.

Institutional approval to conduct research at Island Health requires both research ethics review and operational review.

#### **Operational Review and Considerations**

additional Island Health resources.

equests to continue or amend an existing research study must meet all of the following criteria:	
	Does not require research staff to enter Island Health's facilities or spaces (for example, medical records) that would not otherwise be accessed.
	Does not require research staff to remain longer in areas of Island Health's facilities to conduct research-related activities than they would under normal duties (for example, nurses who may be involved in research studies outside of regular duties).
	Does not require any in-person meetings or interaction between research team members.
	Does not require Island Health resources of additional time/attention of Directors or Managers to assess any new requirements or changes to the proposed research protocols.
	Does not require that participants attend in person protocol assessments that do not meet the criteria described in the March 20 <sup>th</sup> notice or are not part of standard of care that would be provided outside of the conduct of a study.
	Does not introduce any additional factors not listed above that increase the risk of COVID-19 transmission to staff, patients, families or research team members or require the use of

NOTE: An exception may be made on a case-by-case basis if documented evidence of regulatory requirements that mandate continuation or amendment of a particular study is provided.

#### **Research Ethics Reviews**

<u>Island Health's Research Ethics Boards (Clinical and Health REBs) Guidance</u> and its <u>Standard Operating</u>
<u>Procedure for Research Ethics Board Review during Publically Declared Emergencies</u> provide information related to Research Ethics review during the COVID-19 public health crisis.

## Our previously stated principles regarding health research during the COVID-19 public health crisis continue to apply:

- 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.

## For questions related to operational review considerations for existing research or amendments to existing research, please contact:

Kim Horie, Research Administrative Coordinator Kimberly. Horie@viha.ca

We recognize and appreciate the impact has 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 more information and updates related to COVID-19, please visit:

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