Island Health Research Ethics Boards (Clinical and Health REBs) Guidance during COVID-19 Outbreak

In light of the COVID 19 pandemic, and the rapidly changing landscape, the Island Health REBs advise investigators to consider if their research protocols could be modified or temporarily stopped, and stop personal contacts, laboratory visits or trips into clinics and hospitals. Researchers with drugs, treatments or medical devices that may be effective in treating or diagnosing COVID-19 are encouraged to contact the Public Health Authority of Canada for assistance with facilitating clinical trials.

For both clinical and health studies involving human participants, investigators should consider if their research protocols could be modified or delayed, to stop personal contacts and maintain social distancing. Specifically, in some research settings in-person participant interactions should be replaced with telephone or online communication. Considerations include the nature of your protocol, the type of participants engaged in the research, and any additional risk that may arise by switching from in-person to virtual communication. Revised participant consents or consent addendums will be required (e.g., to update privacy considerations with use of different communication channels).

Where research staff are feeling unwell, care should be taken to stay home to prevent transmission of any illness. If COVID-19 is known or suspected, Public Health protocols should be followed.

While TCPS 2 (2018) typically requires review and approval of modifications prior to implementation, an exception can be made where the change is necessary to eliminate an immediate risk to participant(s) (Article 6.15). Such changes may be implemented but must be reported to the REB at the earliest opportunity. This could be reported as (a) a formal Sponsor-driven amendment, (b) protocol deviation reports, or (c) a protocol waiver request (a request to temporarily modify the protocol to alter the procedures for site visits, etc.)

Similarly, studies that must comply with the US federal regulations require that the REB review any revision to the protocol before they are implemented except in cases, "where necessary to eliminate apparent immediate hazards to the human subjects." 21 CFR 56.108(a)(4).

Please contact the appropriate REB (HREB or CREB) for your study whenever possible if you are considering revisions to the approved protocol. However, should you determine that changes in your procedures are immediately required, you may implement them, without prior notice to or approval from the REB. You will need to ensure that you are **not** introducing other risks, and you may need to ask participants to sign revised informed consent forms. The changes should be reported to the appropriate REB as soon as possible. If a full revised protocol cannot be completed, a document that describes the changes and explains how they will protect participants can be submitted, along with copies of any new or revised subject-facing materials.

We ask that any Post Approval Activities (PAAs) or emails 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 email 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 and inform Island Health's Research & Capacity Building.

Notification to the sponsor of the study where applicable is required. This is the responsibility of the Investigator.

Where in-person participant contact cannot be modified, delayed or eliminated, due to the nature of the study specifically in the clinical setting, we recommend that study-related personnel call each study participant prior to their visit. Specifically, please ask the participant the following:

- Have they recently travelled outside of Canada?
- Do they have the following symptoms: cough, sneezing, fever, sore throat or difficulty breathing?
- Have they been in close contact with a sick person, especially if they had a fever, cough or difficulty breathing?
- Have they been instructed to be on 14 day isolation?

If they respond with a yes to any of these questions, please consider rescheduling their study visit.

A reminder that where the research involves physical assessments and use of equipment (e.g., metabolic carts, facemasks, mouthpieces, nose clips, straps, turbines, valves, tubing, cannula, treadmills, etc.) disinfection according to manufacturer's standards where applicable is paramount and use of single-use accessories is advisable. In the absence of manufacturers' standards, thorough cleaning between participants is advised. Please see Health Canada's website up-to-date information on prevention and risk. The BC Centre for Disease Control's website is also available.

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