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

December 1, 2020

The Research Ethics & Compliance office and REBs at Island Health continue to monitor the response to COVID-19 and to adjust our practices, recommendations, and supporting materials in step with provincial and other guidelines. On November 19, 2020 – in response to an increase in confirmed COVID-19 cases in BC – the Provincial Health Officer issued an order for province-wide restrictions on social interactions and travel. These orders are in effect until December 7, 2020.

Masks are mandatory in all indoor settings. Island Health's policy requires medical grade masks at all workplaces at Island Health.

For both clinical and health studies involving human participants, researchers 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 continue to 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. If the study is modified, revised participant consents or consent addendums will be required (e.g., to update privacy considerations when using different communication channels such as Zoom online conferencing or similar). These updated study documents should include information to participants regarding researchers' responsibility for contact tracing and the requirement to keep information (separate from study data) for 30-days as per public health orders. This document provides this information for researchers.

It is the responsibility of researchers to follow recommendations from the Public Health Agency of Canada, the BC CDC, WorkSafe BC, and Island Health policies regarding COVID-19. Please refer to the guidance and links here for information regarding research ethics review at Island Health.

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.

Research Ethics & Compliance Office
Island Health
Queen Alexandra Centre for Children's Health
2400 Arbutus Road, Room 205 | Victoria, BC V8N 1V7 Canada

Tel: 250-519-6726
https://www.islandhealth.ca/research-capacity-building/research-ethics-approvals

REB Considerations for Review and Approval during COVID-19 - Updated

The Island Health REBs primary concern is for the safety and welfare of communities and participants during the COVID 19 pandemic. Island Health is also concerned about its staff, patients, and families. Research that can be done using online methods should proceed online.

In circumstances where the nature of the research requires in-person contact, the REBs have developed review procedures designed to ensure that concerns for participant safety and welfare alongside researcher needs (e.g. graduation and funding requirements or deadlines) can be considered. In cases where research cannot be undertaken using online methods AND the benefits of the research outweigh COVID-related risks, in-person research can proceed. The researcher is responsible for demonstrating their need to conduct in-person research using the resources and forms provided.

Operational Review

Operational Review while conducted concurrently to ethical review may reveal additional considerations such as limited resources available at the health authority due to COVID-19 requirements or demands, staffing concerns, and limits to access of onsite services.

Researchers are encouraged to contact directly the departments and offices where their research was taking place to confirm it is appropriate and can be accommodated. Where issues arise, please contact Kim Horie, Research Administrative Coordinator, for assistance. It is possible that additional review may be required given the COVID-19 related circumstances. Research applications still requiring Operational Review will be reviewed as per criteria outlined in notices from Research & Capacity Building.

Conducting In-Person Research

REQUIREMENTS AT A GLANCE

Research Phase	New Application			Renewals or Suspended/Amended during COVID	
Research Type	**In person COVID-related**	**In person NOT COVID-related**		**In person COVID-related**	**In person NOT COVID-related**
Forms Required	Safety Plan Request to Resume or Initiate A Research Study at Island Health form	Safety Plan Request to Resume or Initiate A Research Study at Island Health form		Safety Plan Request to Resume or Initiate A Research Study at Island Health form	Safety Plan Request to Resume or Initiate A Research Study at Island Health form
CREB Application	Include COVID-19 in the Project Title Consider what flexibility in study procedures you may require (e.g., virtual visits, shipping medications, remote monitoring, etc.) and build them into your proposal. Full Board review* (If above minimal risk; this may be harmonized with other sites in BC.) **Ad hoc meetings can scheduled as needed*.	Consider what flexibility in study procedures you may require (e.g., virtual visits, shipping medications, remote monitoring, etc.) and build them into your proposal. Full Board review if above minimal risk		Include COVID-19 in the Project Title Submit an amendment to change study procedures, or a waiver to request a temporary halt of certain procedures for a period of time. Consent forms can either be modified (e.g., COVID-related risks added, changes in study visits, adding remote monitoring, etc.) or an addendum can be added to explain what has changed. Delegated review* *Subject to change if risks are significantly increased*	Submit an amendment to change study procedures, or a waiver to request a temporary halt of certain procedures for a period of time. Consent forms can either be modified (e.g., COVID-related risks added, changes in study visits, adding remote monitoring, etc.) or an addendum can be added to explain what has changed. Delegated review* **Subject to change if risks are significantly increased*
HREB Application	Full Board review* **An ad-hoc committee meeting will be convened for timely review* Include Covid-19 in the Project Title Attach Safety Plan and Resumption Survey (pdf)	Full Board review* will **An ad-hoc committee meeting will be convened for timely review* Attach Safety Plan and Resumption Survey (pdf)		Full Board review* **An ad-hoc committee meeting will be convened for timely review* Include Covid-19 in the Amendment Title Attach Safety Plan and Resumption Survey (pdf)	Full Board review* **An ad-hoc committee meeting will be convened for timely review* Attach Safety Plan and Resumption Survey (pdf)

Researcher Considerations for Research Conducted during COVID-19

Island Health has permitted the return of in-person research with limitations and additional considerations. The REBs are responsible for the review of the ethical concerns raised in the course of a proposed protocol with consideration of the current pandemic state. *The intention of the combined efforts is to limit in-person research to studies that are beneficial to the participants and/or urgent for the research or the researcher*. Please consider the below around conducting in-person research at this time.

Assessing Benefit and Urgency

In-person research on-site and off-site: In-person research should be conducted only if it cannot be conducted online. As examples: research where the results would be affected by connecting online rather than in-person, where the loss of face-to-face interaction would diminish the quality of the data, where it is clinically required to assess participant safety or a serious adverse event(SAE), or where curtailment of the research would mean the loss of valuable services to participants (clinical research considerations (e.g. drug or IP), support groups, therapy-based research, or programs that meet basic needs for food, childcare, and shelter).

Benefit of the research: Consider whether it is of benefit to (a) individual participants, (b) participants sharing common characteristics, or (c) a community or society at large. Examples of benefits could include increased useful knowledge to participants, enhancements to community services and programs, implementation of/or changes to policies leading to positive societal change, such as safer workplace practices or direct program delivery to a particular participant population. For clinical studies, examples may include a potential benefit of the study treatment being delivered to the participant, access to medications not otherwise available (e.g.an extension study waiting for regulatory approval).

Urgency of the research: Consider whether the research needs to be done now, due to special circumstances. For example, is the researcher a student who needs to complete the research to graduate? Is the research dependent on the school year? Is it dependent on real-time pandemic experiences or scheduled events outside the researcher's control? Does the researcher risk loss of funding?

Indigenous Research

Published by the First Nations Health Authority (FNHA) in collaboration with Research Ethics BC (REBC) and offered here as a resource for all researchers who wish to conduct research with First Nations people or communities. The document provides extensive resources and additional readings.

Culturally Safe and Trauma-Informed Practices for Researchers during COVID-19

Public Health Activities during COVID-19

It should be noted that the following articles and the requirement for consent will not apply to public health activities undertaken by federal, provincial and territorial public health officials operating under statutory powers during publicly declared health emergencies (TCPS2, Chapter 6, D, page 86).

Quality Improvement Projects during COVID-19

If you intend to conduct a quality improvement project, we strongly recommend submitting it to the QI Ethics Decision Making Tool and Registry. QI projects are exempt from research ethics review; however, they may present ethical concerns which would benefit from the consults and review offered through Island Health's QI Ethics group.