

NOTICE RESUMPTION AND INITIATION OF NON-COVID-19 RESEARCH

Date: June 2, 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 conduct, review and initiation of non-COVID-19 related clinical trials and clinical/health research projects with some specific case by case exemptions.

Island Health is implementing a multi-phase approach, in alignment with provincial requirements and public health guidance, to resume clinical services and access to facilities with a focus on safety, standards and maintaining capacity to respond to potential future waves of COVID-19.

The resumption and initiation of non-COVID-19 research is aligned with Island Health's COVID-19 recovery plans and includes two concurrent processes that **together**, **when approved**, comprise Institutional Approval to proceed.

- 1. Research Ethics Review: to assess current ethical acceptability
- 2. Operational Review to assess current capacity to support

The Research Ethics processes for non-COVID-19 research are available here.

PRINCIPLES:

- 1. Ensure the safety of research participants, their families, staff, students and research team members and all Island Health staff working in areas where the research occurs.
- 2. Confirm that research studies have plans¹, or procedural amendments, to minimize the potential spread of COVID-19.
- 3. Reduce the risks of delays in start-up or resumption of non-COVID research.
- 4. Optimize efforts to conduct the research remotely wherever possible (in-person behavioral research, focus groups and interviews).²
- 5. Ensure that Island Health's capacity to support the research is confirmed and that workload requirements are supportable by care teams and leaders.
- 6. Continue to monitor COVID-19 as the pandemic evolves provide updates to this policy on a regular basis.

¹ Work Safe BC/Academic Institution requirements

² A guidance document on acceptable virtual tools for research is provided <u>here.</u>

OPERATIONAL REVIEW CONSIDERATIONS

Service and Program Capacity

Island Health has implemented COVID-19 Recovery and Response procedures for its hospitals, surgical services, ambulatory care, emergency department, community health services, long-term care and mental health and substance use departments.

The desired outcomes of these procedures are:

- The thoughtful recovery to normal levels of operation with an emphasis on keeping patient care limited to safe care spaces
- Continued and diligent practices to limit the spread of COVID-19 until community immunity has occurred
 or a vaccine is developed and implemented

The resumption of research activities in a given department or facility, or research that requires specific clinical or diagnostic services, is dependent on:

- 1. Alignment of the study requirements with the area Recovery and Response plan, including safety considerations
- 2. The scope and intensity of services required
- 3. Capacity to support (staffing, procedures/services, equipment or supplies)

Research must not introduce additional risk of COVID-19 transmission to staff, patients or families who are working in, or receiving services at island Health facilities.

Researchers, research team members and research participants must follow Island Health's <u>Essential Visitor</u> <u>Policy</u> while on site.

All studies are expected to have a Safety plan in accordance with academic institution requirements or Work Safe BC policies, as applicable to the study context and setting.

- https://www.worksafebc.com/en/about-us/covid-19-updates/covid-19-industry-information/health-care.
- https://www.worksafebc.com/en/about-us/covid-19-updates/covid-19-returning-safe-operation/in-person-counselling
- https://www.worksafebc.com/en/about-us/covid-19-updates/covid-19-returning-safe-operation/offices

As part of the Safety Plan, research participants must be pre-screened for COVID-19 exposure and symptoms, prior to attending Island Health's facilities for procedures or tests.

Alternatively, amendments to the original study application can be made where applicable (for example, switching from in-person focus groups to virtual meetings).

PRIORTIZATION CRITERIA

Island Health is committed to timely review of non-COVID research and the time required is based on the capacity within the Research Department.

Prioritization criteria for the order of review of non-COVID research include:

- 1. Risks of delaying research to participants
- 2. Mitigation strategies in place for resuming research to minimize risks to participants
- 3. Risks to the integrity of the study, including funding
- 4. Risks associated with meeting degree completion timelines
- 5. Capacity of required Island Health facilities/services to restart

- 6. Availability of a safety plan or study-specific COVID-19 related safety and operational amendments
- 7. Mandated regulatory requirements
- 8. Alignment with Island Health's and Ministry of Health strategic and operational priorities

APPLICATIONS TO RESTART OR INITIATE NEW NON-COVID-19 RESEARCH

Researchers are required to complete an online form to facilitate the review of each study.

This includes new applications as well as resumption of studies that were either in review or approved at the time of suspension.

For questions, please contact:		

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Island Health values its research community and recognizes and appreciates the impact of COVID-19 on researchers. We are committed to a safe restart process aligned with our organizational capacity to support.

More information on Island Health's COVID-19 policies can be found here.