Research Ethics Review, Approvals, and Resumption of Research at Island Health

Island Health's Research Ethics & Compliance office, and REBs are committed to the resumption of research with human participants as soon as possible based on the direction of the Provincial Health Officer and the Health Authority.

Research Ethics approval and operational review equals Institutional Approval at Island Health. The REBs and staff are dedicated to efficiently addressing the work of supporting research for a safe restart for research participants and the community. This document outlines the principles and instructions to be followed to ensure research with human participants (including their data, and biospecimens) can be conducted safely.

Foundational ethical principles applied to the process of review of ethical and operational applications

Responsibilities of Researchers

A fundamental premise of TCPS2 (2018) is that research can benefit human society. In order to maximize the benefits of research, researchers must have academic freedom. Academic freedom includes freedom of inquiry; the right to disseminate the results of that inquiry; freedom to challenge conventional thought; freedom to express one's opinion about the institution, its administration or the system in which one works; and freedom from institutional censorship. With academic freedom comes responsibility, including the responsibility to ensure that research involving humans meets high scientific and ethical standards that respect and protect the participants. Thus, researchers' commitment to the advancement of knowledge also implies duties of honest and thoughtful inquiry, rigorous analysis, commitment to the dissemination of research results, and adherence to the use of professional standards. There is a corresponding responsibility on the part of institutions to defend researchers in their efforts to uphold academic freedom and high ethical, scientific and professional standards (TCPS2 (2018), Chapter 1.A).

Responsibilities of Island Health REBs:

Island Health REBs have a responsibility to: 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; Implement required public health and work safe BC COVID-19 plans to minimize the potential spread of COVID-19, including self-screening for potential symptoms and not coming to Island Health facilities if symptoms are present**; *Optimize efforts to conduct the research remotely where-ever possible*.** This includes in-person behavioural research, focus groups and interviews; Limit adverse risks of delays in start-up or resumption of research while maintaining the integrity of ongoing studies.

Island Health will continue to monitor COVID-19 as the pandemic continues and will advise on any changes to this policy on a regular basis. As such, this guidance is subject to change as rapid restrictions

in Island Health resources/services may occur in response to the public health emergency over time. To see the latest updates from Research and Capacity Building see: https://www.islandhealth.ca/research-capacity-building.

In addition, from the ethical lens, the following guidance in terms of research should be considered:

1. No large in-person gatherings as part of the research.
2. Routine daily screening has been mandated by the Public Health Officer and is required for all individuals working in research spaces. All faculty, staff, and students should self-screen for symptoms daily before coming to sites. Individuals who have symptoms of a cold, flu, or COVID-19 with any coughing or sneezing are not permitted onto Island Health sites.
3. Permissions for research that may use PPE will be limited or non-existent unless there is access or provisions made within the research itself.
4. Researchers should consider equity, diversity, and inclusion (EDI) and equal access in their planning for research resumption and should not compel students or employees to work on sites if those individuals have concerns about their safety or are experiencing other COVID-related barriers (refer to Island Health's HR return to work plans.
5. Where research involves multiple institutions, researchers consider and apply the requirements for restarting research across all sites in order to comply with safety precautions related to COVID-19.

The review of applications submitted for ethical and operational review will manage capacity, flow, and address the issues within the Health Authority of managing the resumption of clinical care. These may present challenges for operational review and approval. This are further addressed in notices from Research & Capacity Building.

Resumption of Research Ethics review priorities remain applications with:

- ☐ COVID-19 focus
- ☐ Increased risks of delaying research to participants

Additional criteria considered for the resumption or initiation of non-COVID research include:

- ☐ Mitigation strategies in place for resuming research to minimize risks to participants
- ☐ Risks to the integrity of the study, including funding
- ☐ Risks associated with meeting degree requirements
- ☐ Capacity of Required Island Health Facilities/Services to Restart
- ☐ Availability of a safety plan or study-specific COVID-19 related safety and operational amendments
- ☐ Mandated regulatory requirements
- ☐ Alignment with Island Health's and Ministry of Health strategic and operational priorities

Research Safety Plans and Related Questions

The REBs will not approve a safety plan related to COVID-19. This is because these plans are out of the scope of research ethics review. They will be reviewed to ensure they are present as per guidelines from the institutions involved in the research, and they will be considered through the ethical imperative of ensuring safety for participants in research. As per TCPS2 (2018), while it is not a formal part of REB responsibilities, an REB may raise concerns about the safety of researchers as part of its communications. Based on the level of risk, the REB may consider referring these concerns for review by an appropriate body within the institution.

As such, the REBs will only acknowledge this documentation.

The following questions must be answered of all research applications including currently approved applications when an amendment or renewal is submitted to our office at this time:

1. **Please describe how you will meet the current COVID-19 related public health directives/Island Health requirements around the conduct of this research study?**
2. **Please attach a safety plan for REB acknowledgement. If you do not have one, please address how you will meet current public health directives during your research project.**
3. **Please confirm that these safety expectations will be met within your email, which we will keep on file as your attestation.**

Please ensure these are addressed when submitting. This can be done through a separate document or attached to your protocol or proposal. The REB will review and may have additional provisos.

REB Requirements for *NEW* Research Related to COVID-19

If your new study involves the study of COVID-19, please make this clear by including "COVID-19 Research" in the study title and email the identified contact for the relevant REB (see below) with the study number, and title with the COVID-19 suffix.

- If your COVID-19-related study requires in-person contact, it will be subject to a Full REB (above minimal risk) review. An ad-hoc committee will be convened to ensure timely review.
- If your COVID-19-related study can be conducted entirely online, an expedited review and approval may be completed, after which research can proceed.
- Concerns have been raised at a provincial and local level about the number of COVID-19 related research projects and the additional burden this may place on some participant populations and potential risks of harm these projects may introduce. This could be especially true in the case of participants with pre-existing physical and mental vulnerabilities. This may mean additional questions will be asked of a project that involves these groups.

REB Requirements for *NEW* Research (Non-COVID-19)

Research ethics applications can be submitted as normal through the portal (ROMEO), or if your application is harmonized through Research Ethics BC (REBC), please submit through RISe. Please contact Research Ethics personnel if you require assistance.

There will need to be confirmation by researchers that all other institutional requirements and requirements are being met (e.g. exemption forms, or other required documentation) as well as Public Health Office and Ministry, etc. This MUST be documented in the application whether on Romeo or RISe. Applications that are incomplete will be returned to the researcher.

Previously Approved Research

Research that has received ethics approval before the COVID-19 restrictions were implemented can proceed but must meet current public health directives (https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/health-professionals.html). If your study involves in-person contact AND research staff are unable to work remotely AND use of health authority resources (sites, staff, or patients) is required, then an Amendment should be submitted to the REB. If you need to alter your methods to replace or modify in-person contact, please review the sections below for additional instructions before you submit your Amendment.

Renewals and Amendments

Amendments should be submitted for all changes to research at this time. Where there is imminent risk to participants, changes can be made without immediately notifying the REB (TCPS2 (2018), Article 6.15). As per the earlier memo, 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).

Community Research Sites

For research (new or previously approved) that takes place only outside of Island Health facilities or does not require any Island Health resources:
Community research sites are expected to meet current public health directives (https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/health-professionals.html). You will need to notify the REB of any changes that will be made to a study protocol to ensure participant and staff safety. This may be reported as an amendment or a protocol waiver request. If your site has a safety plan, please submit a copy for acknowledgement.

Operational Review

Researchers with Institutional Approvals are encouraged to contact the departments and offices where their research was taking place to confirm it is appropriate. 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.

Compliance

Guidance for clinical research training can be found at: https://www.islandhealth.ca/research-capacity-building/conduct-research-island-health/training-compliance.

If you have any questions, please contact Tracy Wong, Research Compliance Facilitator.

Additional Information

BC's clinical research ethics boards have developed a rapid ethical review process for Provincial clinical research pertaining to COVID-19. For more information, see https://researchethicsbc.ca/rapid-review-process/

Researchers with drugs, treatments or medical devices that may be effective in treating or diagnosing COVID-19 are encouraged to contact the Public Health Agency of Canada for assistance with facilitating clinical trials.

Please see Health Canada's Notice to clinical trial sponsors on the management of clinical trials during the COVID-19 outbreak. Please contact your institutional clinical trials operations or your research ethics board for more information.

Clinical researchers should also be aware of the US FDA Guidance on Conduct of Clinical Trials of Medical products during the COVID-19 outbreak.

Clinical researchers using Fecal Matter Transplant (FMT) should be aware of the US FDA Guidance regarding safety guidance to avoid transmission of FMT in human fecal matter: https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/safety-alert-regarding-use-fecal-microbiota-transplantation-and-additional-safety-protections

Contact Information for Research Ethics & Compliance Office

RECO personnel continue to work remotely. Please refer here for contact information.