COVID-19
Provincial Research Ethics Process

1 BACKGROUND

1.1 On March 18th, 2020, the pandemic known as COVID-19 was declared as a public health emergency for British Columbia (BC). TCPS2 – Chapter 6: Research Ethics Review during Publicly Declared Emergencies, Article D: [https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter6-chapitre6.html#21](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter6-chapitre6.html#21) states: “Once an emergency has been designated a publicly declared emergency, authorities may exercise special responsibilities and powers to deal with the situation, and the exercise of those responsibilities may temporarily modify normal procedures or practices.”

1.2 The clinical Research Ethics Board (REBs) in BC review and approve research for Island Health, Fraser Health, Interior Health, Northern Health, Providence Health Care, BC Children’s and Women’s Hospitals, Vancouver Coastal Health (UBC CREB) and BC Cancer. These REBs are responsible for the review and approval of the clinical research that takes place in the province that involves health-authority patients (including hospitals, public health clinics, care homes, and other facilities owned-operated by the health authorities).

1.3 The capacity of clinical REBs is becoming stretched due to remote meeting and working requirements, as well as the influx of activities related to new studies on COVID-19, changes to research studies limiting in person enrollment and requiring that only essential clinical care research studies continue. It is relatively certain that many clinicians will be pulled into front-line care delivery and some will be conducting clinical research studies that are related to COVID-19 or are a part of essential clinical care.

1.4 In order to streamline the process for ethical review of clinical studies on COVID-19, it is more efficient for a study to be approved by one REB for all clinical REBs in the province. The current policies and procedures in place permit REBs to give full reciprocity on a case-by-case basis (see Appendix ‘A’ Template Language for Maximal Reciprocity). The current policies and procedures would ideally be superseded for clinical studies on COVID-19 to full reciprocity as a requirement, allowing for ethical review by the Board of Record on behalf of all REBs (partner participation in the review is possible, as described in Step 8 of REVIEW PROCESS below).

1.5 The Institutional/operational approvals required by the institutions will be separate from this process but are expected to be streamlined accordingly to allow for efficient approvals for research in all health authorities.

2 SCOPE

2.1 This process applies to any research involving human participants within British Columbia that:
   a) is identified as related to COVID-19; and
b) is clinical in nature\(^1\) including non-regulated trials; and

c) is under the auspices of at least one BC institution; and/or

d) involves BC patients and/or their data or biological materials.

2.2 The exception will be BC Cancer studies on COVID-19, which will be managed in accordance with the current [Guidance on BC Cancer Studies](#).

2.3 The requirement for a research collaborator from each health authority to be identified at the outset of the ethics application will be rescinded, allowing for the approval by the REB more quickly. The study cannot be conducted at a site until institutional/operational requirements are met for that site, including the identification of a local collaborator for the project.

2.4 The Board of Record is predetermined by the Provincial Research Ethics Platform (PREP) algorithm, but is expected to be able to conduct a review and issue provisos to the investigator as quickly as possible, but within a maximum of five (5) calendar days. If this cannot be committed to by the REB in question, they must identify as much to the other affected institutions and another REB will be chosen to conduct the review. This process is intended to guide the REB offices and members during the process of the public health emergency of COVID-19.

2.5 The Board of Record, as determined within this process, will remain the Board of Record and retain responsibility for ethical review of the study until its closure, regardless of whether the public health emergency has ended or not.

2.6 REBC will work with the REBs to ensure the process is working smoothly, and at a minimum, will review the whole process three (3) months from date of implementation to determine if any changes are required.

### 3 DEFINITIONS

Each of the following terms has the meaning ascribed to it in this Section, unless otherwise specifically provided or otherwise required by the context:

3.1 "Board of Record" means the REB that will serve as the primary authority for the ethical oversight of the research.

3.2 “Clinical Trial” is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioural health-related outcomes.

3.3 "Continuing Research Ethics Review" means any review of ongoing research conducted by a REB occurring after the date of initial REB approval and continuing throughout the life of the project to ensure that all stages of a research project are ethically acceptable in accordance with the principles in the Policy.

---

\(^1\) Clinical research is research with the goal of improving the diagnosis, and treatment (including rehabilitation and palliation), of disease and injury; improving the health and quality of life of individuals as they pass through normal life stages. Clinical research usually encompasses research on, or for the treatment of, patients. (Canadian Institutes of Health Research)
3.4 “Human Participant” means an individual whose data, biological materials, or responses to interventions, stimuli, or questions by a researcher are relevant to answering the research question(s). Also referred to as a ‘participant’, ‘subject’ or ‘research subject’.

3.5 “Maximal Reciprocity” is the highest level of reciprocity acceptable to a party for its ethical review requirements for a multi-jurisdictional study, based upon the relationship of the relevant parties to each other, the perceived risks of the study, the relevant parties’ institutional policies, and any other considerations and judgments that a party may deem, in its sole discretion, to be relevant.

3.6 “Multi-jurisdictional Research” means research involving multiple institutions and/or multiple research ethics boards (REBs).

3.7 "Research Ethics Board” or "REB" is a body of researchers, community members, and others with specific expertise (e.g., in ethics, in relevant research disciplines, etc.) established by an institution to review the ethical acceptability of all research involving humans conducted within the institution’s jurisdiction or under its auspices.

3.8 “Provincial Research Ethics Platform” or “PREP” is an electronic module for the application, review, approval (initial and ongoing), and closure of multi-jurisdictional studies in BC. PREP is housed within the UBC’s Research Information System or “RISe”.

3.9 “Sponsor” is an individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial (ICH E6 (R2), 1.53)

4 REVIEW PROCESS

4.1 The researcher will complete the research ethics application in PREP/RISe.

4.2 The Board of Record (BoR) will be determined in accordance with the programmed algorithm, based upon:
   a) Location of majority of participants and/or study team;
   b) Which institution is best placed to mitigate risk to participants/data;
   c) The expertise of the involved REBs (for example: Children’s and Women’s Hospitals for pediatric populations);
   d) Proportion of the study that is hospital-based and community-based; and
   e) Other unique factors that the participating boards agree are relevant.

4.3 The judgment of the most appropriate REB to be designated as Board of Record is to be initially made by the REB the algorithm designated as Board of Record, and in consultation with participating REBs if determined necessary, in accordance with the current agreed Harmonized Ethical Review Guidance. This consultation must be done within a few hours in order to avoid delay to the five (5) day review requirement set out in this process. For example, if the population is primarily pediatric, the REB with the most relevant expertise is Children’s and Women’s Hospital’s REB, and they would be designated as the REB if the algorithm did not select them automatically; similarly, UBC CREB would be designated as the Board of Record for BCCDC studies.

4.4 The Board of Record will have responsibility for the ethical oversight of the project, including initial review and approval, and continuing research ethics reviews even after this process is no longer in place for new reviews.
4.5 The Board of Record will determine from the application if the study is intended or likely to expand into the other Health Authorities and follow the below guidance a. or b. accordingly. For example, a small-scale feasibility study will not likely affect more than one jurisdiction for the initial study, but a provincial biobank will likely expand into all Health Authorities.

a. **If the study is likely to expand into other Health Authorities**, the board of record will ‘harmonize’ the study in PREP/RiSe, including all health authorities even if they were not originally included in the application. This gives all Health Authorities access to the application in PREP but does not notify them specifically or request that they review the application. The Board of Record will then select the “Assign for Harmonized Review” button. ‘Assign for Harmonized Review’ gives partnering boards notification that they are involved in a study and requests participation in the review process. The Board of Record should **ONLY** include sites that have a local PI identified in the study application. If no local PI’s are identified in the application, the BoR does not need to do this step at this time. The Board of Record will include the following language in assigned for harmonized review to help all other added REBs understand which locations the researcher has included at this time:

“The study has identified xxxx and yyyy only at this time. All health authorities are being added to the study as per the COVID-19 Provincial Research Ethics Process. If/when the research is to be activated at the additional locations, an amendment will be submitted to provide the names of collaborators.”

i. The Board of Record will review the application to ensure that there are adequate descriptions included of how the study affects other institution(s) where a local PI has been identified and they are appropriately listed in section 4.2.C of the application form.

ii. If the Board of Record determines that a privacy review is necessary and the current membership does not include a Research Privacy Advisor, it will refer the project to the PHSA Research Privacy Office to conduct a privacy review at the same time as the ethics review and the outcome of the review will be recorded in PREP/RiSe. This privacy review addresses BC privacy law requirements and should not trigger any additional privacy reviews.

iii. The other institutions in the study, where a local PI has been identified, will be asked to assign one member from their REB to participate in the review process if they so choose, but they will be required to add their provisos to PREP/RiSe within 24 hours of being contacted, and in advance of the Board of Record completing its review, or at a virtual full-board meeting if arranged. If they are unable to respond with comments prior to the review being finalized, the review and approval will proceed without their input. The other participating institutions will **not** choose the option to be notified of the proviso response, and the Board of Record will have responsibility for resolving the provisos with the researcher.

iv. When local PI’s are identified at Health Authorities after initial approval, the PI should submit an amendment indicating the name of the local PI. The BoR will invite the joining site to review the study at this time and institutional approvals can initiate. **The joining site must review the amendment within 5 days or accept direct reciprocity.** Any additional review should be site specific only.

b. **If the study is unlikely to expand into other Health Authorities**, the Board of Record will process the study within the timelines outlined in this guidance but will include only sites where a local PI is identified.

i. If a site is later identified, an amendment can be submitted as per iv above.
4.6 Where the Board of Record does not represent a health authority, they must include at least one member of a health authority REB in the review process.

4.7 The REB comments and review decisions will be documented in PREP/RISe, as per standard procedure, and PREP/RISe automatic notification will be sent out to the researcher.

4.8 The notification will not trigger any duplicate research ethics review but is intended for information purposes only so relevant partner organizations and/or REBs can document the research.

4.9 Each institution is responsible for educating their institutional researchers that when undertaking multi-jurisdictional research, it is the researcher’s responsibility to ensure:

a) their local REB is notified about the research;

b) any other required reviews and/or approvals are obtained prior to commencing the research (ie institutional or departmental approvals); and

c) they are aware of and will comply with all applicable and relevant institutional policies, procedures, and processes within those jurisdictions where the research is being conducted

5  CERTIFICATE OF APPROVAL

5.1 The Certificate of Approval will be issued by the Board of Record REB.

5.2 Relevant institutions/sites would be listed on the Certificate of Approval, including the logos of all the affected health authorities as per 5.a. (list all Health Authority) or 5.b. (list only participating sites) above.

5.3 The following note should be copied into the text box below the certificate of approval for studies that fall into 5.a.

“This study has been reviewed and approved under the COVID-19 Provincial Research Ethics Process: https://researchethicsbc.ca/rapid-review-process/. The research ethics review has been completed for all Health Authorities. The research team can start at XX and YY sites, identified in this application once appropriate institutional approvals are obtained. If they wish to start research at another Health Authority where a local PI has not yet been identified, they should submit an amendment to this application, indicating the new Health Authority PI and this amendment will be reviewed for site specific concerns within 5 days.”

6  PROCESS FOR NON-REGULATED CLINICAL TRIALS

Non-regulated clinical trials to be conducted across multiple locations in BC, where one Principal Investigator leads the study for the province, will be reviewed according to Pilot Model for Harmonization of Clinical Trials.

7  PROCESS FOR REGULATED CLINICAL TRIALS

The process for review and approval of regulated clinical trials will be addressed in a separate process.
Appendix ‘A’ Template Language for Maximal Reciprocity

The following language was used by various institutions to form Standard Operating Procedures for maximal reciprocity between Institutions who signed the BC Research Ethics Review Reciprocity Agreement dated April 15, 2013.

BACKGROUND:

In 2013, the University of British Columbia (UBC), Simon Fraser University (SFU), the University of Northern British Columbia (UNBC), the University of Victoria (UVic), Fraser Health Authority, Interior Health Authority, Northern Health Authority, and Vancouver Island Health Authority (Island Health), signed the “BC Research Ethics Review Reciprocity Agreement.” This agreement set out the groundwork for maximal reciprocity between these institutions.

In order to realize the maximal reciprocity outlined in that Agreement, the conditions under which one of these REBs can defer to one of the other REBs for review of an application, is outlined below. In line with the TCPS2 (2014) concept of proportionality, the REBs will review multijurisdictional applications using one of the following approaches:

a) Direct Reciprocity: The REB will accept the review of another REBC network REB without review.

b) Partial Review: The REB will look at the application for site specific requirements and participate either by providing their provisos in addition to the Board of Record provisos, or by participating in the full board review representing their institution.

c) Full Review: The REB will conduct a full review as Board of Record.